IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Amiram STEINBERG

Serial No: **08/842,680**

Group Art Unit: **3738**

Examiner: **D.J. Isabella**

Filed : **April 15, 1997**

For : **BONE GROWTH PROMOTING IMPLANT**

REPLY FOR REQUEST FOR RECONSTRUCTION

Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

In response to the Request for Reconstruction mailed September 14, 2001, Applicant submits the reconstructed file for the above-identified patent application. The papers include a copy of the application as filed, including a Declaration and an IDS with an unsigned Declaration. A Notice to File Missing Parts of the Application and the response to the Notice to File Missing Parts of the Application including a signed Declaration are enclosed.

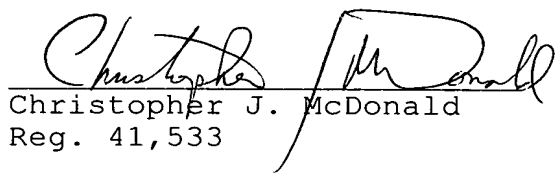
Also enclosed are: the restriction requirement dated August 12, 1998, and a response to the restriction requirement; a second restriction dated March 1, 1999, and a response to the second restriction requirement; Paper #10, holding the claim election of March 22, 1999 informal and a further response to restriction requirement. The Notice of Abandonment, dated April 14, 2000, holding the application abandoned for failure to file a response to the Office Action of August 3, 1999 is enclosed.

The enclosed papers reflect correspondence to and from the Patent Office concerning the above-identified patent application and reconstructs the Patent Office file. A new Power of Attorney is also enclosed. Please enter the Power of Attorney into the file and send all future correspondence to:

Christopher J. McDonald, Esq.
Hoffman, Wasson & Gitler, P.C.
2361 Jefferson Davis Highway
Suite 522
Arlington, Virginia 22202

If any additional material is needed, the Examiner is urged to contact the undersigned attorney.

Respectfully submitted,



Christopher J. McDonald
Reg. 41,533

January 24, 2002

HOFFMAN, WASSON & GITLER, PC
2361 Jefferson Davis Highway
Suite 522
Arlington, VA 22202
(703)415-0100

Attorney's Docket: A-7617.RRR/cat

Please type a plus sign (+) inside this box — [+]

PTO/SB/82 (11/98)
Approved for use through 6/30/99. OMB 0651-0035

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REVOCATION OF POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	08/842,680
Filing Date	April 16, 1997
First Named Inventor	Amiram Steinberg
Group Art Unit	3736
Examiner Name	David J. Isabella
Attorney Docket Number	A-7617

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application:

[✓] A Power of Attorney or Authorization of Agent is submitted herewith.

OR

[X] Please change the correspondence address for the above-identified application to:

[X] Customer Number 20741

OR

20741

[X] Firm or Individual Name	HOFFMAN, WASSON & GITLER, PC				
Address	2361 Jefferson Davis Highway				
Address	Suite 522				
City	Arlington				
Country	U.S.	State	VA	ZIP	22202
Telephone	(703) 415-0100	Fax	(703) 418-2768		

I am the:

[✓] Applicant.

[ ] Assignee of record of the entire interest
Certificate under 37CFR 3.73(b) is enclosed

SIGNATURE of Applicant or Assignee of Record

Name	Amiram Steinberg
Signature	Amiram Steinberg
Date	Dec 4th 2000

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED
JAN 29 2002
TECHNOLOGY CENTER 3700

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MAR 25 2002
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

POWER OF ATTORNEY

Docket No.

A-7617

Name of Applicant: **Amiram Steinberg**
Address of Applicant:

Title: **BONE GROWTH PROMOTING IMPLANT**

Serial No., if Any: **08/842,680**
Filed: **April 15, 1997**

TO THE ASSISTANT COMMISSIONER FOR PATENTS

The Assistant Commissioner for Patents
Washington, D.C. 20231

Honorable Sir:
I hereby appoint:

Christopher J. McDonald	**Reg. 41,533**
Martin P. Hoffman	**Reg. 22,261**
Mitchell B. Wasson	**Reg. 27,408**
Stewart L. Gitler	**Reg. 31,256**

as principal attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please direct all future correspondence to:

HOFFMAN, WASSON & GITLER, P.C.
2361 Jefferson Davis Highway
Suite 522
Arlington, VA 22202
(703) 415-0100

By: Amiram Steinberg
Amiram Steinberg

cc: 20741

Dated: Dec 4th 2000

31843
2714

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

10c

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/842,680	04/25/97	STEINBERG	

0M32/0414

NORMAN H. ZIVIN
COPPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER	
ISABELLA, T	

ART UNIT	PAPER NUMBER
	12

DATE MAILED: 04/14/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

53112 NHZ

Notice of Abandonment

Application No.	Applicant(s)
08/842,680	STEINBERG
Examiner	**Group Art Unit**
ISABELLA, DAVID J.	3738

This application is abandoned in view of:

☒ applicant's failure to timely file a proper response to the Office letter mailed on *Aug 3, 1999* .

☐ A response (with a Certificate of Mailing or Transmission of _____) was received on _____, which is after the expiration of the period for response (including a total extension of time of ____ month(s)) which expired on _____ .

☐ A proposed response was received on _____, but it does not constitute a proper response to the final rejection.

(A proper response to a final rejection consists only of: a timely filed amendment which places the application in condition for allowance; a Notice of Appeal; or the filing of a continuing application under 37 CFR 1.62 (FWC)).

☒ No response has been received.

☐ applicant's failure to timely pay the required issue fee within the statutory period of three months from the mailing date of the Notice of Allowance.

☐ The issue fee (with a Certificate of Mailing or Transmission of _____) was received on _____ .

☐ The submitted issue fee of $_____ is insufficient. The issue fee required by 37 CFR 1.18 is $_____ .

☐ The issue fee has not been received.

☐ applicant's failure to timely file new formal drawings as required in the Notice of Allowability.

☐ Proposed new formal drawings (with a Certificate of Mailing or Transmission of _____) were received on _____ .

☐ The proposed new formal drawings filed _____ are not acceptable.

☐ No proposed new formal drawings have been received.

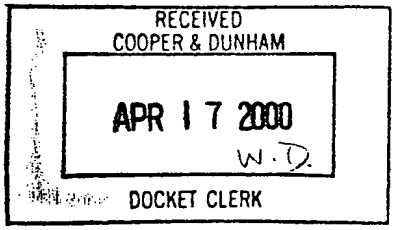
☐ the express abandonment under 37 CFR 1.62(g) in favor of the FWC application filed on _____ .

☐ the letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

☐ the letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

☐ the decision by the Board of Patent Appeals and Interferences rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

☐ the reason(s) below:



David J. Isabella
Primary Examiner

Office Action Summary

Application No.	Applicant(s)
08/842,680	STEINBERG
Examiner	**Group Art Unit**
ISABELLA, DAVID J.	3738

☒ Responsive to communication(s) filed on *Jul 13, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *THREE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-56* is/are pending in the application.

Of the above, claim(s) *4-7, 21-34, 38-48, and 50-56* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 8-20, 35-37, and 49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "10" and "3" have both been used to designate the implant. Correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-3,8-20, 35-37 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite. There is no structural nexus between the interface portion and the support structure. There is no structure defining an "interface".

Claim 2 is indefinite. Claim 1 fails to posiitvely set forth a structure defining the implant and therefor, there is no support for the "central core".

Claim 3, recitation of "truss-like" is indefinite for failing to positively limit the same.

Claim 9 should recite the implant having a surface defining a bone engaging interface and the interface comprises a plurality of support elements protruding therefrom.

Claim 10 is indefinite. It is not clear what characteristic is being adapted for fit within a bone canal.

Claim 11 is redundant to claim 9.

Claim 12, there is no physical nexus between the cable and the support structure.

Claim 13, there is no physical nexus between the cable, the bridge element and the support structure.

Claim 14, see claim 12 supra.

Claim 15 is indefinite. It is not clear how and by what means asymmetric tension is effected to the cables.

Claim 16 should positively recite the cables as having means for adjustment before, during, and/or after.

Claim 17 fails to further define the structure of claim 14.

Claim 18 should recite that the medication is adminstered after implantation in the bone.

Claim 19 is indefinite. It is not clear if the medication and the coated material are one and the same.

Claim 20 is indefinite for the improper alternative language. BMP and medication are not equivalent elements.

Claim 35, see rejections to claims 1 and 9 supra.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1,2,8,9,10,11 and 35-37 are rejected under 35 U.S.C. 102(b) as being clearly anticpated by either of Day or Weber. .

Each of Day and Weber disclose an implant comprisng an interface portion and a central portion wherein the interface portion is deformable upon insertion into a prepared bone canal.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 18,19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Day or Weber as applied to claim 1 above, and further in view of Muller-Lierheim.

The coating of implant surfaces with growht factors to enhance biocompatibility is taught by Muller-Lieheim. To coat the implant of Day or Weber with growth factors for increase tissue compatibility would have been obvious from the teachings of Muller-Lierheim.

7. Claims 1,3 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumbleton, et al in view of Day.

Dumbleton, et al discloses an implant comprising an interface and a support core. The support core comprising a plurality of rods. Day teaches the use of an implant having an interface formed with deformable elements for better fixation into the prepared bone. To form the interface of Dumbleton, et al with deformable elements for better fixation to the bone would have been obvious from the teachings of Day.

Election/Restriction

8. Claims 4-7,21-34,38-48,50-56 withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention and species. Election was made **without** traverse in Paper No. 10.

9. Applicant's election without traverse of claims 1-3,8-20, 35-37 and 49 in Paper No. 10 is acknowledged.

Allowable Subject Matter

10. Claims 12-17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Isabella whose telephone number is (703) 308-3060. The Examiner's Supervisor, Mickey Yu, may be reached at (703) 308-2672. The group receptionist may be reached at (703) 308-0858.

Should Applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 308-3590. Should Applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

DAVID J ISABELLA

PRIMARY EXAMINER

GROUP 3700

dji

August 28, 1999

Applicant Amiram Steinberg

Client 1582 File No. 53112 Atty. NHZ

Date July 9, 1999

Kindly acknowledge receipt of the accompanying

Applicant	:	Amiram Steinberg
Serial No.	:	08/842,680
Filed	:	April 15, 1997
For	:	BONE GROWTH PROMOTING IMPLANT

FURTHER RESPONSE TO RESTRICTION REQUIREMENT

by placing your receiving date stamp hereon and returning to us.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Amiram STEINBERG

Serial No.: 08/842,680

Filed : April 15, 1997

For : BONE GROWTH PROMOTING IMPLANT

Group A.U.: 3738

Examiner : D.J. Isabella

Assistant Commissioner for Patents
Washington, D.C. 20231

FURTHER RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In further response to the Office Action dated March 1, 1999, and the supplemental communication dated June 18, 1999, application hereby elects the species defined as follows:

Group A: Support element 1 - truss

Group B: Combination 1 - cable

The claims readable thereon are claims 1-3, 8-20, 35-37 and 49.

The previous traverse of the election requirement, having been predicted on a misunderstanding of the requirement, is withdrawn. The requirement for election, as now understood, is not traversed. It is noted, however, that if generic claims are found allowable, claims to nonelected species will be examined on the merits in the present application.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization

is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Dated: 7/9, 1999

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Norman H. Zivin 7/9/99
Norman H. Zivin Date

Norman H. Zivin
Reg. No. 25,385
c/o Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400
Attorney for Applicant

08/842680

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	10

DATE MAILED: 6/18/99 BM
7/18/99

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

1. ☒ The communication filed 3/22/99 is informal/non-responsive for the reason(s) checked below and should be corrected. APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER OR UNTIL THE EXPIRATION OF THE PERIOD FOR RESPONSE SET IN THE LAST OFFICE ACTION (WHICHEVER IS LONGER) WITHIN WHICH TO CORRECT THE INFORMALITY.

   a. ☐ The amendment to claim(s) _____, filed _____, fails to comply with the provisions of 37 C.F.R. 1.121 and is accordingly held to be non-responsive. A supplemental paper correcting the informal portions and complying with the rule is required.

   b. ☐ The paper is unsigned. A duplicate paper or ratification, properly signed, is required.

   c. ☐ The paper is signed by _____, who is not of record. A ratification or a new power of attorney with a ratification, or a duplicate paper signed by a person of record, is required.

   d. ☐ The communication is presented on paper which will not provide a permanent copy. A permanent copy, or a request that a permanent copy be made by the Office at applicant's expense, is required, see M.P.E.P. 714.07.

   e. ☒ Other APPLICANT MUST PICK ONE ELEMENT FROM EXIT GROUP.

2. ☐ In accordance with applicant's request, THE PERIOD FOR RESPONSE FROM THE OFFICE ACTION DATED _____ IS EXTENDED TO RUN _____ MONTH(S).
   No further extension will be granted unless approved by the Commissioner. 37 C.F.R. 1.136 (b)

3. ☐ Receipt is acknowledged of papers submitted under 35 U.S.C. 119 which papers have been made of record in the file.

4. ☐ Other

David Isabella

David J. Isabella
Primary Examiner

PTOL-327 (rev. 10-79)

NOTICE TO APPLICANT

Applicant Amiram STEINBERG S.N. 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYJ

Date March 16, 1999

Kindly acknowledge receipt of the accompanying

1. Response to Claim Restriction Requirement with certificate of mailing dated March 16, 1999

DUE DATE: APRIL 1, 1999

by placing your receiving date stamp hereon and returning to us.

Applicant Amiram STEINBERG S.N. 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYJ

Date March 16, 1999

Kindly acknowledge receipt of the accompanying

1. Response to Claim Restriction Requirement with certificate of mailing dated March 16, 1999

DUE DATE: APRIL 1, 1999

by placing your receiving date stamp hereon and returning to us.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Amiram STEINBERG

Serial No.: 08/842,680

Filed : April 15, 1997

For : BONE GROWTH PROMOTING IMPLANT

Group A.U.: 3738

Examiner : D.J. Isabella

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO CLAIM RESTRICTION REQUIREMENT

Sir:

In the Office Action dated March 1, 1999 in the above-identified application, the Examiner states that election is required under 35 U.S.C. § 121 of one of the allegedly distinct species of Group A, which the Examiner indicates is related to support elements such as a truss, a mesh, and a spring, for example, and Group B, which the Examiner indicates is related to a combination of an implant and other structures such as a cable, a sleeve, and a lining/sleeve.

The Examiner states that Applicant is required under

I hereby certify that this paper is being deposited this date with the U.S. Postal Service in first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

3/16/99

Norman H. Zivin Date
Reg. No. 25,385

35 U.S.C. § 121 "to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable." The Examiner alleges that currently, claims 1, 2, 8-11, and 18-20 are generic.

Claims 1-20 and 35-52 are currently pending in this application, with claims 21-34 and 53-56 having been withdrawn from examination by the Examiner as being drawn to a non-elected invention.

The Office Action does not indicate which of the two Groups, A or B, the pending claims belong to.

In response to the requirement under 35 U.S.C. § 121, Applicant hereby elects, with traverse, to prosecute the species of Group A. Applicant has determined that claims 1-11, 18-20, 35-37, 39, 40, and 49-52 belong to Group A.

Applicant, however, respectfully requests that the Examiner reconsider and withdraw the election requirement for at least the following reasons. Under 35 U.S.C. § 121, election of species may be required if two or more independent and distinct species are claimed in one application. The species of Group A and Group B are not distinct because the term "distinct" means that each of the species are capable of separate manufacture, use, or sale as claimed, and are patentable (novel and unobvious) over each other. MPEP § 802.01. The species of Group A relates to a deformable bone implant comprising an interface portion for interfacing with a bone, and a support structure for supporting the interface

portion. The species of Group B relates to a deformable bone implant comprising an interface portion for interfacing with a bone, a support structure for supporting the interface portion, and at least one of adjustable cables for adjusting the tension in the support structure, a sleeve element surrounding the support structure, and a lining interposed between the sleeve element and the support structure. Specifically, the species of Group A and the species Group B are related because the claims of both Groups recite deformable bone implants, and the elements of the Group B claims are used in conjunction with the Group A claims to improve the characteristics and performance of the implants. Therefore, Applicant maintains that the species are not distinct and the requirement to elect a single species is not proper.

Applicant further maintains that it would not be a serious burden on the Examiner if restriction is not required, because a search of the prior art for Group A, drawn to a deformable bone implant, would necessarily identify art for Group B, drawn to a deformable bone implant with additional structural elements for improving the characteristics and performance of the deformable bone implant.

Accordingly, in view of the preceding remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the election of species requirement.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required,

authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Norman H. Zivin, Reg. No. 25,385
Attorney for Applicant
COOPER & DUNHAM LLP
1185 Avenue of the Americas
New York, N.Y. 10036
Tel.: (212) 278-0400

NHZ/LSYJ

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

NORMAN H. ZIVIN
COPPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 03/01/99
4/1/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 1996-404-496/40510

2 - Mail Copy

Office Action Summary

Application No.	Applicant(s)
08/842,680	STEINBERG
Examiner	**Group Art Unit**
ISABELLA, DAVID	3738

☒ Responsive to communication(s) filed on *Nov 6, 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *ONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-56* is/are pending in the application.

Of the above, claim(s) *21-34 and 53-56* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-56* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. Applicant's election of Group 1 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 21-34 and 53-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Upon further review of the specification and the claims, Examiner has found that the application contains subject matter directed to patentably distinct species.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Group A: Support element

1-truss

2-mesh

3-spring

4-two materials with different Young's modulus

5-inflatable

6-longitudinal support

7-trough-like

Group B: Combination of Implant and other structures 1-cable

2-sleeve

3-lining/sleeve.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1,2,8-11,18-20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. A telephone call was made to Mr. Norman Zivin on 2-15-99 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Isabella whose telephone number is (703) 308-3060. The Examiner's Supervisor, Mickey Yu, may be reached at (703) 308-2672. The group receptionist may be reached at (703) 308-0858.

Should Applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 308-3590. Should Applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

DAVID J ISABELLA

PRIMARY EXAMINER

GROUP 3700

dji

February 16, 1999

Dkt. 1582/53112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	:	Amiram STEINBERG
Serial No.	:	08/842,680
Filed	:	April 15, 1997
For	:	BONE GROWTH PROMOTING IMPLANT
Group A.U.	:	3738
Examiner	:	D.J. Isabella

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO CLAIM RESTRICTION REQUIREMENT

Sir:

In response to PTO Paper No. 6 dated August 12, 1998 requiring restriction of inventions under 35 U.S.C. § 121, Applicant hereby elects, with traverse, to prosecute Group I (claims 1-20 and 35-52).

The restriction requirement is traversed because it is believed that all of the claimed inventions relate to a bone-growth promoting implant, are sufficiently related to each other, and are capable of being used together so as to warrant being examined in one patent application.

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

11/3/98

Norman H. Zivin Date
Reg. No. 25,385

Respectfully submitted,

Norman H. Zivin, Reg. No. 25,385
Attorney for Applicant
COOPER & DUNHAM LLP
1185 Avenue of the Americas
New York, N.Y. 10036
Tel.: (212) 278-0400

NHZ/LSYJ

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYI

Date November 3, 1998

Kindly acknowledge receipt of the accompanying

1. Response to Claim Restriction Requirement with certificate of mailing dated November 3, 1998

DUE DATE: NOVEMBER 12, 1998

by placing your receiving date stamp hereon and returning to us.

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYI

Date November 3, 1998

Kindly acknowledge receipt of the accompanying

1. Response to Claim Restriction Requirement with certificate of mailing dated November 3, 1998

DUE DATE: NOVEMBER 12, 1998

by placing your receiving date stamp hereon and returning to us.

UNITED STATES D RTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/[illegible]	[illegible]	[illegible]	[illegible]

NORMAN H. ZIVIN
COPPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER
[illegible]

ART UNIT	PAPER NUMBER
1[illegible]	

DATE MAILED: [illegible]

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

☆U.S.GOVERNMENT PRINTING OFFICE 1996-411-516/40275

2-File Copy

Office Action Summary

Application No.	Applicant(s)
08/842,680	STEINBERG
Examiner	**Group Art Unit**
ISABELLA, DAVID	3738

☒ Responsive to communication(s) filed on *Aug 6, 1998*

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *THREE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-56* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-56* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

8/12/98
11/12/98
2/12/99

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20,35-52 drawn to deformable bone implant, classified in class 623, subclass 16.

II. Claims 21-33, drawn to bone brace, classified in class 606, subclass 72.

III. Claim 34, drawn to a cerclage device, classified in class 606 , subclass 74.

IV. Claim 53, drawn to bone cement, classified in class 606, subclass 86.

V. Claims ~~53~~ 54 - 56, drawn to intramedullary nail, classified in class 606, subclass 62.

2. The inventions are distinct, each from the other because of the following reasons: Inventions of group 1 and group 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The implant of group 1 has a core member surrounded by a deformable layer whereas the brace of group 2 is a sleeve element with a trough. The sleeve is designed to encircle the bone.

3. Inventions of group 1 and group 3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The implant of group 1 has a core member surrounded by a deformable layer whereas the brace of group 3 is a sleeve element with support elements attached to the sleeve. The sleeve is designed to encircle the bone.

4. Inventions of group 1 and group 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have uniquely different functions. The cement of group 4 may be used in combination with other bone fixation devices and does not require the implant of group 1.

5. Inventions of group 1 and group 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The implant of group 1 has a deformable layer that engages the bone whereas the nail of group 5 is intended to be driven into the intramedullary canal.

6. Inventions of group 2 and group 3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

The implant of group 2 has a trough member attached to a cable element whereas the brace of group 3 is a sleeve element with support elements attached to the sleeve.

7. Inventions of group 2 and group 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have uniquely different functions. The cement of group 4 may be used in combination with other bone fixation devices and does not require the implant of group 2.

8. Inventions of group 2 and group 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The implant of group 2 is designed to be place on the outer surface of the bone whereas the nail of group 5 is intended to be driven into the intramedullary canal.

9. Inventions of group 3 and group 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have uniquely different functions. The cement of group 4 may be used in combination with other bone fixation devices and does not require the implant of group 3.

10.

Inventions of group 3 and group 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The implant of group 3 is designed to be place on the outer surface of the bone whereas the nail of group 5 is intended to be driven into the intramedullary canal.

11. Inventions of group 4 and group 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have uniquely different functions. The cement of group 4 may be used in combination with other bone fixation devices and does not require the implant of group 5.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

13. A telephone call was made to Norman Zivin on 8-6-98 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Isabella whose telephone number is (703) 308-3060. The Examiner's Supervisor, Mickey Yu, may be reached at (703) 308-2672. The group receptionist may be reached at (703) 308-0858.

Should Applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 308-3590. Should Applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

DAVID J ISABELLA

PRIMARY EXAMINER

GROUP 3700

dji

August 6, 1998

Dkt. 1582/53112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applications	:	Amiram STEINBERG	Group A.U.	:
Serial No.	:	08/842,680	Examiner	:
Filed	:	April 15, 1997		
For	:	BONE GROWTH PROMOTING IMPLANT		

Assistant Commissioner for Patents
Washington, D.C. 20231

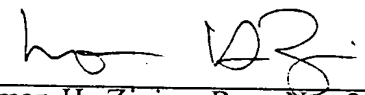
Sir:

LETTER SUBMITTING VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS AND REQUEST FOR REFUND

In connection with the above-identified application, submitted herewith is a Verified Statement Claiming Small Entity Status.

Applicant respectfully requests the Office to refund any overpayment of fees by crediting the overpayment to Deposit Account No. 03-3125.

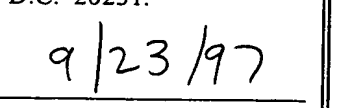
Respectfully submitted,



Norman H. Zivin, Reg. No. 25,385
Attorney for Applicant
COOPER & DUNHAM LLP
1185 Avenue of the Americas
New York, N.Y. 10036
Tel.: (212) 278-0400

NHZ/LSYJ
encl.

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



9/23/97

Norman H. Zivin
Reg. No. 25,385

Date

Attorney Docket No.: **1582/53112**

Applicants or Patentees: **Amiram STEINBERG**
Serial or Patent No.:
Filed or Issued:
Title of Invention or Patent: **BONE GROWTH PROMOTING IMPLANT**

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS UNDER (37 C.F.R. §1.9(f) AND §1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. §1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office, with regard to the invention entitled **BONE GROWTH PROMOTING IMPLANT** described in:

_____ the specification filed herewith
__X__ application Serial No. 08/842,680 filed April 15, 1997
_____ patent No. _____ issued _____

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R.§1.9(c) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. §1.9(d) or a nonprofit organization under 37 C.F.R. §1.9(e).

If I have assigned, granted, conveyed, or licensed, or if I am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention to any person, concern, or organization, these are listed below.

Name: **Limber Ltd.**
Address: **P.O. Box 176**
Avihail 42910
ISRAEL

_____ Individual
__X__ Small Business Concern
_____ Nonprofit Organization

I acknowledge the duty to file in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on

which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b).

Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small business entities. 37 C.F.R. §1.27.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Inventor: Amiram STEINBERG

Signature of Inventor: Amiram Steinberg

Date: April 16- 97

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYJ

Date September 23, 1997

Kindly acknowledge receipt of the accompanying

1. Letter Submitting Verified Statement Claiming Small Entity Status And Request For Refund
2. Signed Verified Statement Claiming Small Entity Status
3. Certificate of Mailing

by placing your receiving date stamp hereon and returning to us.

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYJ

Date September 23, 1997

Kindly acknowledge receipt of the accompanying

1. Letter Submitting Verified Statement Claiming Small Entity Status And Request For Refund
2. Signed Verified Statement Claiming Small Entity Status
3. Certificate of Mailing

by placing your receiving date stamp hereon and returning to us.

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty NHZ/LSYJ

Date September 23, 1997

Kindly acknowledge receipt of the accompanying

1. Response to Notice To File Missing Parts -- Filing Date Granted
2. Signed Declaration and Power of Attorney
3. Copy of Notice To File Missing Parts -- Filing Date Granted
4. Check #29916 for $130 for the surcharge
5. Certificate of Mailing

by placing your receiving date stamp hereon and returning to us.

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty NHZ/LSYJ

Date September 23, 1997

Kindly acknowledge receipt of the accompanying

1. Response to Notice To File Missing Parts -- Filing Date Granted
2. Signed Declaration and Power of Attorney
3. Copy of Notice To File Missing Parts -- Filing Date Granted
4. Check #29916 for $130 for the surcharge
5. Certificate of Mailing

by placing your receiving date stamp hereon and returning to us.

COOPER & DUNHAM LLP
PTO ACCOUNT
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

REMITTANCE ADVICE		
1382		
5312		

1-108
210

P 29916

MARINE MIDLAND BANK N.A.
FIFTY SECOND STREET OFFICE
NEW YORK, N.Y.

PAY SPECIMEN **DOLLARS**

DATE	TO THE ORDER OF	CHECK AMOUNT
9-23-97	**COMMISSIONER OF PATENTS AND TRADEMARKS**	130 00

242136-01-95

⑈029916⑈ ⑆021001088⑆ 011⑈77924⑈ 1⑈

Dkt. 1582/53112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applications	:	Amiram STEINBERG	Group A.U.	:
Serial No.	:	08/842,680	Examiner	:
Filed	:	April 15, 1997		
For	:	BONE GROWTH PROMOTING IMPLANT		

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTENTION: BOX MISSING PARTS

Sir:

RESPONSE TO NOTICE TO FILE MISSING PARTS -- FILING DATE GRANTED

In response to the Notice To File Missing Parts Of Application -- Filing Date Granted dated September 18, 1997, a copy of which is attached hereto, submitted herewith is a signed Declaration and Power of Attorney for the above-identified application.

Also submitted herewith is the fee of $130 for the surcharge.

The Office is hereby authorized to charge any additional fees which may be required in connection with this submission and to credit any overpayment to our Deposit Account No. 03-3125.

Respectfully submitted,

Norman H. Zivin, Reg. No. 25,385
Attorney for Applicant
COOPER & DUNHAM LLP
1185 Avenue of the Americas
New York, N.Y. 10036
Tel.: (212) 278-0400

NHZ/LSYJ
encl.

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

9/23/97

Norman H. Zivin
Reg. No. 25,385

Date

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BONE GROWTH PROMOTING IMPLANT

the specification of which
(check one)

___ is attached hereto.

_X_ was filed on April 15, 1997 as

Application Serial No. 08/842,680

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Number	Country	Filing Date	Priority Claimed Yes	No

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status

And I hereby appoint Norman H. Zivin, Reg. No. 25,385; Jay H. Maioli, Reg. No. 27,213; Donald S. Dowden, Reg. No. 20,701; William E. Pelton, Reg. No. 25,702; Peter J. Phillips, Reg. No. 29,691; Gerald W. Griffin, Reg. No. 18,886; Ivan S. Kavrukov, Reg. No. 25,161; Christopher C. Dunham, Reg. No. 22,031; John P. White, Reg. No. 28,678; Robert D. Katz, Reg. No. 30,141; Wendy E. Miller, Reg. No. 35,615, and Lock See Yu-Jahnes, Reg. No. 38,667, and each and all of them, all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, NY 10036 (Tel. (212) 278-0400), my attorneys or agents, each with full power of substitution and revocation, to receive the patent, to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Please address all communications, and direct all telephone calls, regarding this application to

Norman H. Zivin — Reg. No. 25,385
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036
(212) 278-0400

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or
First joint inventor Amiram STEINBERG

Inventor's signature Amiram Steinberg

Citizenship Israel — Date of Signature April 16 97

Residence Avihail, Israel

Post Office Address Limber Ltd.
P.O. Box 176
Avihail 42910
ISRAEL

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE

SEP 2 2 1997

DOCKET CLERK

DATE MAILED: 11/18/97
3/18/98

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted ALONG WITH THE PAYMENT OF A SURCHARGE for items 1 and 3-6 only of $ 130.00 for a ☒ large entity ☐ small entity in compliance with 37 CFR 1.27. The surcharge is set forth in 37 CFR 1.16(e). Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required above to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☒ large entity ☐ small entity (verified statement filed), is $ 130.00

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $_____ to complete the basic filing fee and/or file a verified small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $_____, including any multiple dependent claim fees, are required.
Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☒ 3. The oath or declaration:
- ☒ is missing.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are:
- ☐ missing.
- ☐ by a person other than inventor or person qualified under 37 CFR 1.42, 1.43, or 1.47.

A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $_____ processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules.
See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

☐ 9. OTHER:

Direct the response and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the response.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

*U.S. GPO: 1996-404-496/405

NHZ

PTO-103X
(Rev. 8-95)

FILING RECEIPT

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Patent and Trademark Office
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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
08/842,680	04/15/97	3308	$1,802.00	1582/53112	7	56	6

NORMAN H. ZIVIN
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NEW YORK NY 10036

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Applicant(s)

AMIRAM STEINBERG,,.

FOREIGN FILING LICENSE GRANTED 09/17/97
TITLE
BONE GROWTH PROMOTING IMPLANT

PRELIMINARY CLASS: 623

(see reverse)

NH2

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08/842,680	04/15/97	STEINBERG	A 1582/53112

0242/0918

NOT ASSIGNED

NORMAN H. ZIVIN
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3308

DATE MAILED: 09/18/97
11/18/97
3/18/98

NOTICE TO FILE MISSING PARTS OF APPLICATION
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An Application Number and Filing Date have been assigned to this application. However, the items indicated below are missing. The required items and fees identified below must be timely submitted ALONG WITH THE PAYMENT OF A SURCHARGE for items 1 and 3-6 only of $ 130 for a ☐ large entity ☐ small entity in compliance with 37 CFR 1.27. The surcharge is set forth in 37 CFR 1.16(e). Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required above to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☒ large entity ☐ small entity (verified statement filed), is $ 130.00.

☐ 1. The statutory basic filing fee is:
- ☐ missing.
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Applicant must submit $ _____ to complete the basic filing fee and/or file a verified small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $ _____, including any multiple dependent claim fees, are required.
Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☒ 3. The oath or declaration:
- ☒ is missing.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are:
- ☐ missing.
- ☐ by a person other than inventor or person qualified under 37 CFR 1.42, 1.43, or 1.47.

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☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

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An oath or declaration listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $ _____ processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

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See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

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FORM PTO-1533 (REV.7-96) **PART 3 - OFFICE COPY** *U.S. GPO: 1998-404-496/40515

Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYJ

Date July 14, 1997

Kindly acknowledge receipt of the accompanying

1. Information Disclosure Statement
2. Form PTO-1449
3. Copies of 9 references listed on form PTO-1449

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Applicant Amiram STEINBERG 08/842,680

Client Limber (1582) File No. 53112 Atty. NHZ/LSYJ

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Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 53112	Serial No. 08/842,680
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)	Applicants Amiram STEINBERG	
	Filing Date 04//15/97	Group

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	AA	4 8 0 8 1 8 6	02/28/89	Smith			
	AB	5 2 4 6 4 6 1	09/21/93	Tepic			
	AC	5 3 6 4 8 3 9	11/15/94	Gerhart et al.			
	AD	5 3 7 6 1 2 0	12/27/94	Sarver et al.			
	AE	5 3 9 3 7 3 9	02/28/95	Bentz et al.			
	AF	5 4 5 8 6 4 3	10/17/95	Oka et al.			
	AG	5 4 8 0 4 4 9	01/02/96	Hamilton et al.			
	AH	5 5 1 0 4 1 8	04/23/96	Rhee et al.			
	AI	5 5 2 2 8 9 4	06/04/96	Draenert			
	AJ						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	BA							
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this from with next communication to applicant.

Dkt. 1582/53112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applications	:	Amiram STEINBERG	Group A.U.	:
Serial No.	:	08/842,680	Examiner	:
Filed	:	April 15, 1997		
For	:	BONE GROWTH PROMOTING IMPLANT		

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to Applicant's duty of disclosure, the information listed in the attached Form PTO-1449 is brought to the attention of the Examiner. Copies of the information identified herein are also provided.

It is respectfully requested that the information cited in annexed Form PTO-1449 be considered by the Examiner in connection with the above-identified application, and that such art be made of record in said application.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the items are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of the particular items, it will assist in identifying fields of search and in making as full and complete a

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

7/14/97

Norman H. Zivin
Reg. No. 25,385

Date

search as possible.

The filing of this Information Disclosure Statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

To the best of Applicant's knowledge, this Information Disclosure Statement is being filed before the date of mailing of a first Office Action on the merits in connection with this case.

No fee is believed necessary in the filing of this Information Disclosure Statement. However, the Office is hereby authorized to charge any fees which may be required in connection with this Information Disclosure Statement and to credit any overpayment to our Deposit Account No. 03-3125.

Early and favorable consideration of the case is respectfully requested.

Respectfully submitted,

Norman H. Zivin, Reg. No. 25,385
Attorney for Applicant
COOPER & DUNHAM LLP
1185 Avenue of the Americas
New York, N.Y. 10036
Tel.: (212) 278-0400

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Dkt. 1582/53112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Amiram STEINBERG

Serial No. :

Filed :

For : BONE GROWTH PROMOTING IMPLANT

1185 Avenue of the Americas
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March 21, 1997

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SIR:

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Respectfully submitted,

Norman H. Zivin, Reg. No. 25,385
Attorney for Applicants
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Norman H. Zivin, Esq.
COOPER & DUNHAM LLP
1185 Avenue of the Americas
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URGENT!

Applicant New Application of Amiram STEINBERG

Client 1582 (Limber Ltd.) File No. 53112 Atty. NHZ/LSYJ

Date April 15, 1997

Kindly acknowledge receipt of the accompanying

New Application in PTO:

Specification (48 pages, 56 claims, 6 ind.), 7 sheets of informal drawings, Express Mail certificate, Transmittal Form (in triplicate), and check # 28161 for $1802.00 for filing fee.

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Applicant New Application of Amiram STEINBERG

Client 1582 (Limber Ltd.) File No. 53112 Atty. NHZ/LSYJ

Date April 15, 1997

Kindly acknowledge receipt of the accompanying

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Specification (48 pages, 56 claims, 6 ind.), 7 sheets of informal drawings, Express Mail certificate, Transmittal Form (in triplicate), and check # 28161 for $1802.00 for filing fee.

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Docket No. 1582/53112

IN THE U.S. PATENT AND TRADEMARK OFFICE

ASSISTANT COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D. C. 20231

Sir:

Transmitted herewith for filing are the specification (15 pages) and claims (16 total) of the patent application of:

Amiram STEINBERG for
Inventor(s)

BONE GROWTH PROMOTING IMPLANT
Title of Invention

Also enclosed are:

X 7 sheets of X informal _____ formal drawings.

_____ An Oath or Declaration of Applicant(s).

_____ A Power of Attorney.

_____ An Assignment of the invention to _____.

_____ A Preliminary Amendment.

_____ A Verified Statement Claiming Small Entity Status Under 37 C.F.R. § 1.9(f) and § 1.27(b).

The filing fee is calculated as follows:

CLAIMS AS FILED, LESS ANY CLAIMS CANCELLED BY AMENDMENT

	Number Filed		Number Extra*		RATE SMALL ENTITY	RATE OTHER ENTITY		FEE SMALL ENTITY	FEE OTHER ENTITY
Total Claims	56 - 20	=	36	x	$ 11	$ 22	=	$ ---	$ 792
Indep. Claims	6 - 3	=	3	x	$ 40	$ 80	=	$ ---	$ 240
Multiple Dependent Claims Presented: Yes____ No X					$125	$250	=	$ ---	$ ---
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__X__ Three copies of this sheet are enclosed.

_____ A certified copy of previously filed foreign application No._____ filed in _____ on _____. Applicant hereby claims priority under 35 U.S.C. § 119.

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Respectfully submitted,

NORMAN H. ZIVIN, Reg. No. 25,385
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1582/53112

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR LETTERS PATENT

TITLE: BONE GROWTH PROMOTING IMPLANT

INVENTOR: AMIRAM STEINBERG

Norman H. Zivin
Reg. No. 25,385
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New York, New York 10036

BONE-GROWTH PROMOTING IMPLANT

FIELD OF THE INVENTION

The present invention relates generally to bone implants. More specifically, the present invention relates to bone-growth promoting implants and implants that promote the growth of composite bone material.

BACKGROUND OF THE INVENTION

Conventional bone prostheses or implants that are known in the art generally include a metal portion constructed of steel or titanium inserted in and fixedly attached to a bony portion of a patient's body. For example, conventional implants for stems of articulating joints or for nail-like implants used for intramedullary fixation to support bones during healing of fractures are constructed of metal. The nail-like implants are usually, but not always, removed when healing is complete.

Current implant technology may be divided into two broad categories: implants which require reaming of an inner canal in the bone before insertion of the implant, generally typical of relatively thick implants; and implants which do not require reaming of a bone canal, generally typical of relatively thin implants. Thin implants are easier to insert and they enable better nourishment of the bone and

faster healing. However, thin implants provide a less stable support structure for the bone.

Several problems are associated with conventional bone implants due to a mismatch between materials properties of the bone and the metal implant. For example, contact between the metal implant and the bone may cause fretting wear of the bone. Also, a difference in materials properties such as Young's modulus and thermal expansion coefficient between the metal implant and the bone may result in poor anchoring of the metal implant to the bone, which may cause discomfort to the patient, especially during weather changes. Furthermore, conventional metal implants provide virtually no shock absorption or damping.

It is generally known that a bone grows or generates new bone tissue according to the level of stress to which it is subjected within an identified range of stress levels that is less than or equal to a certain maximum stress level but greater than or equal to a certain minimum stress level. One problem with conventional metal implants is that they tend to distribute stress unevenly to the surrounding bone, with some surrounding bone areas receiving excessive stress levels and other surrounding bone areas receiving less than optimal stress levels. In extreme cases where the amount of stress imparted to a surrounding bone area is too low, the conventional metal implant may

in inducing or promoting continuous bone growth or bone reinforcement for strengthening the bone.

In order to overcome the aforementioned problems, a number of implants with resilient portions have been proposed in International Application No. PCT/IL96/00098, which was filed September 4, 1996 and invented by the inventor of the present invention, the disclosure of which is incorporated herein by reference. This PCT application discloses various resilient joint prostheses and bone implants that provide shock absorption and promote bone development and growth after implantation. In addition, the PCT application discloses bone implants that are sufficiently flexible that they deform to adapt to various and changing curvatures of the bone.

OBJECTS AND SUMMARY OF THE INVENTION

In view of the above-mentioned considerations, an object of the present invention is to provide an improved bone implant that promotes bone development and growth after implantation, and that improves bone strength through the formation of a composite bone material.

Another object of the present invention is to provide a means for controlling the distribution of stress within a bone and for producing a stress field having an intensity and pattern that acts to prevent bone degeneration

and promote growth of new bone tissue to strengthen selected regions of the bone.

Yet another object of the present invention is to provide a means for producing and controlling micro-movement along a substantially continuous surface of a bone that interfaces and interacts with an implant to promote improved generation of new bone tissue from the micro-movement.

The present invention provides implants with new features that are not disclosed in the PCT application PCT/IL96/00098 invented by the inventor of the present invention.

According to the present invention, a high degree of flexibility and control is imparted to a nail-like implant by using a "spar" construction with adjustable tension cables and longitudinal structural members. The tension cables provide curvature control and support, and rigidity against bending and buckling of the nail-like implant. The longitudinal structural members and the tension cables become an integral part of a composite regenerated bone, which has a substantially increased strength over bone regenerated through the use of conventional implants, regardless of whether the nail-like implant remains inside the bone or whether a majority of the implant (except for the longitudinal structural members) is later removed. The flexibility of the implant is controlled

by specifically varying the structural geometry and stiffness of certain portions of the implant, and by adjusting the tension in selected tension cables during and/or after the implantation operation to thereby adjust the stiffness of the implant. When the longitudinal structural members are inserted into the bone they have at most a low and generally uniform tension level, and preferably the structural members are free of tension during insertion. After insertion, the tension cables may be adjusted to provide additional stiffness to the longitudinal structural members and to produce a desired curvature therein by imparting asymmetric or non-uniform levels of tension thereto.

The present invention creates a stronger regenerated bone by providing a new type of cross-section for a bone implant and by promoting the growth of a composite bone structure.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a cross-sectional view of a bone implant inserted inside a bone canal according to an embodiment of the present invention;

Fig. 1B is a perspective view of a portion of the bone implant of Fig. 1A showing various constructions of support elements according to an embodiment of the present

invention;

Fig. 1C is a perspective view of a portion of the bone implant of Fig. 1A showing an alternative construction of support elements according to an embodiment of the present invention;

Fig. 2A is a cross-sectional view of a bone implant having support elements according to another embodiment of the present invention;

Fig. 2B is a cross-sectional view of a support element of Fig. 2A;

Fig. 2C is a cross-sectional view of a bone implant inserted inside a bone canal according to another embodiment of the present invention;

Fig. 3A is a perspective view of a support element of Fig. 2A;

Fig. 3B is a perspective view of a brace element externally attached to a fractured bone;

Fig. 4A is a longitudinal cross-sectional view of a bone implant according to one embodiment of the present invention;

Fig. 4B is a perspective view of an embodiment of a core of the bone implant having one or more tapered ends according to the present invention;

Fig. 4C is a longitudinal cross-sectional view of tension cables anchored to a support element of the bone

implant according to an embodiment of the present invention;

Fig. 5 is a perspective view of a tension cable and a woven sleeve element according to an embodiment of the present invention;

Figs. 6A and 6B are cut-away views showing tension cables embedded in a web according to an embodiment of the present invention; and

Fig. 7 is a cut-away view showing an improved interlocking nail system according to an embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the present invention are described below with reference to the accompanying drawings, in which like reference numerals represent the same or similar elements.

It is generally known that a body recognizes a minimum level of stress in its bones. New bone cells are generated when an amount of stress is exerted thereto that falls within a preferred range of values that are above a certain lower limit and below a certain upper limit. A conventional stem-type or nail-type implant is constructed to have an average geometric shape that does not conform to the three-dimensionally curved surfaces of a bone canal in which the implant is inserted. In addition, contact between

the implant and the bone occurs at random regions and is generally not sufficiently continuous to promote optimal bone growth. Because of the randomness of the contact between the implant and the bone, the forces exerted by the implant on the bone produce random stress levels within the bone. Only regions in which the amount of stress exerted on the bone is within a biologically acceptable range are recognized by the body so that new bone cells are generated at those recognized regions. Regions with stress levels below the lower limit or above the upper limit are not recognized by the body resulting in no generation of new bone cells. Thus, the body is prevented from rebuilding its skeletal strength.

The present invention provides a means to control the amount and the distribution of stress imparted by an implant to an adjacent bone, and also provides a means to effect micro-movement at interface regions between the bone and the implant. The implants of the present invention conform to the three-dimensionally curved surfaces of a bone canal such that substantially continuous regions of the bone canal interface with protruding support elements of the implant. The substantially continuous regions include surfaces that contact or interface with support elements with multiple fingers spaced reasonably close to each other, and are positioned to produce a continuous distribution of

stress with a desired stress field pattern to promote bone tissue generation and to even tailor bone growth to favor certain bone regions over other regions.

Bone deflection combined with deflection of the implant creates movement in the contact or interface regions, including actual shear movement of the bone relative to the implant, and shear stress in sub-surface regions beneath the contact regions even where there is no actual relative movement. Such micro-movement and micro-change in the stress distribution promotes generation of new bone cells and growth of new bone tissue.

Means for generating and controlling the amount and distribution of stress and for producing micro-movement include:

a) controlling the stiffness of the implant and/or providing means for adjusting the stiffness of the implant, in which reaction of the bone and the implant to bending is adjusted by adjusting tension cables, and in which curvature of the implant is adjusted by adjusting the tension cables; and

b) designing protruding support elements that have an appropriate geometry and size and that are made of certain appropriate materials.

Turning now to the drawings, Fig. 1A shows a bone implant 10 inserted inside a bone 9, according to an embodiment of the present invention. The implant 10 includes a flexible composite central portion or core 12 embedded or molded inside an interface portion 13. The core 12 may be solid or hollow and is preferably formed of a composite material which may be reinforced with a high-performance material such as DYNEEMA™, which is a fiber made from ultra-high molecular weight polyethlyene, for example. The interface portion 13 includes a tubular layer 14 and a plurality of support elements 15 radially protruding outwardly therefrom. The support elements 15 contact the bone 9 by snugly fitting inside a bone canal 4 of the bone 9. Preferably, the support elements 15 occupy only a fraction of the bone canal 4, and zones 3 are located between respective support elements 15 to accommodate natural spongy bone as well as bone marrow. Therefore, the implant 10 permits the spongy bone zones 3 and the bone marrow to internally nourish the bone 9 through the bone canal 4, which is unlike conventional prior art devices that occupy nearly the entire bone canal so that the bone is nourished only from outside of the bone.

Fig. 1B is a perspective view of a portion of the bone implant 10. The support elements 15 may extend longitudinally along the entire length of the implant 10, as

indicated by reference numeral 5. Alternatively, the support elements 15 may be comprised of two or more longitudinal segments, as indicated by reference numerals 6 and 7. The support elements 15 also may have various shapes. For example, reference numeral 16A shows a standard-type support element having a straight lateral profile and a trapezoidal cross section, and reference numeral 16B shows a spring-type support element having a straight lateral profile and an arcuate or hook-like cross section. According to a preferred embodiment, the support elements 15 deform during insertion of the implant 10 into the bone canal 4 to produce a snug fit that presses against an inner wall of the bone 9 (see Fig. 1A), thereby fostering an excellent and substantially continuous fit of the implant 10 to a patient's specific bone geometry.

The implants 10 may be used in conjunction with a method for adapting an implant to a particular bone by means of a computer-aided bone geometry duplicator, as disclosed in PCT application PCT/IL96/00098, which was invented by the inventor of the present invention. According to this method, the computer-aided duplicator is used inside the operating room to cut the implant 10 to a specific desired shape during an operation.

In a typical implantation operation in which a nail-like implant is inserted into a patient, the patient's

bone is drilled to accommodate the implant's particular shape. For implants having stems, such as stems attached to articulating joints, the bone drilling and shaping is done by the surgeon performing the implantation operation. The surgeon uses various files and reamers to prepare the bone for receiving the stem therein. Typically, a number of reamers of various sizes from small to large are used to ream a cavity in the bone and shape the cavity to correspond to the shape of the stem.

According to the present invention, less bone is removed than in the typical implantation operation, and mostly spongy bone material is removed instead of the dense bone material that is reamed out in a conventional implantation operation, which can reduce considerably the strength of the remaining bone. A spoon may be used as a scooping device for removing the spongy bone material to thereby create a cavity in the bone into which an implant of the present invention, with its protruding and flexible support elements, is inserted. The scooping device may contain one or more sensors attached to an elongated flexible core of the scooping device so that when the core is inserted into the cavity the sensors contact and press outwardly against the cavity surface to generate surface geometry data that is fed into a computer. Alternatively, a sensing apparatus separate from the scooping device may be

used to generate the surface geometry data for the cavity. The surface geometry of the cavity may also be determined using various diagnostic techniques such as MRI and/or other tomographic techniques.

Once the surface geometry of the cavity is known, a compact computerized shaping tool, adapted for use in an operating room environment, may be used to shape the implant to fit the cavity. For an implant having support elements 16A (see Fig. 1B), the implant may be formed by first using the shaping tool to produce the implant without the support elements 16A, and then individually machining each of the support elements 16A one at a time, similar to duplicating a key, to produce a substantially close three-dimensional fit of the implant in the cavity.

Fig. 1C illustrates an alternative construction of the support elements 15, according to an embodiment of the present invention. The support elements 15 may include tapered stub-type protrusions 17, substantially deformable and springy hook-type protrusions 18, or tapered stub-type hollow protrusions 19. The hook-type and hollow protrusions 18, 19 deform during insertion into the bone canal 4 and press against an inner wall of the bone 9 (see Fig. 1A), thereby providing an excellent fit to the patient's specific bone geometry. According to a preferred embodiment, the tapered stub-type protrusions 17 have a slender profile,

allowing them to deflect during insertion of the implant 10.

The support elements 15 may also be comprised of other protrusions of various desired shapes. For example, reference numeral 20 shows a support element consisting of a tapered stub-type protrusion with at least one channeled groove 20A formed therein for receiving a tension cable (not shown), which is described hereinbelow. (The term "cable" represents any longitudinal member with an arbitrary cross section, and may be formed of materials such as woven elements, rods, bars, and the like.) Some of the protrusions may be cut using a computer-aided bone geometry duplicator to produce a nearly exact customized fit.

Fig. 2A is a cross-sectional view showing various types of support elements 115, according to another embodiment of the present invention. Each of the support elements 115 include a trough portion 21, a floor 22, and side walls 23. As indicated by reference numeral 150, the support elements 115 may be made of two separate portions, such as a trough portion 21 having a male connecting member 24 forming a first portion that mates with a female slot member 25 formed between a pair of raised or serrated walls 26 extending from the interface portion 13 forming a second portion, for example.

Fig. 2C is a cross-sectional view showing a bone implant 10 inserted inside a bone 9 according to another

embodiment of the present invention. The implant 10 includes a trough portion 21 constructed as an integral part of the interface portion 13. Protruding portions 160 serve as support elements 115 for the implant 10. Zones 3 are located between respective protruding portions 160 to accommodate natural spongy bone as well as bone marrow, thereby permitting the bone 9 to be nourished internally from within the bone 9. The zones 3 may also be used as a mold for the growth of new bone tissue.

A computer-aided bone geometry duplicator may be used to cut the raised walls 26, for example along an orientation line indicated by a-a, as shown in Fig. 2B, so that the trough portion 21 is tailored to snugly press against the inner wall of the bone 9. The computer-aided duplication device takes into account the dimensions of the trough portion 21, which preferably is of a uniform section. A number of different connections between the trough portion 21 and the interface portion 13 are possible, including a smooth fit, a spring fit, a click-on fit, or a serrated fit. The computer-aided bone geometry duplicator may also be used to custom-cut the protruding portions 160 of the bone implant 10 of Fig. 2C.

As indicated by reference numeral 151 in Fig. 2A, the support elements 115 also may be formed of at least one integral portions connected to the trough portion 21 and

having a spring-type connecting member (not shown) or a hollow-type connecting member 28 with a void 27 therein. Both types of connecting members deform during insertion of the implant 10 into the bone canal 4 to snugly fit and press against the inner wall of the bone 9 (see Fig. 2A), thereby fostering an excellent and substantially continuous fit to the patient's specific bone geometry. In addition, the trough portion 21 may be provided with fingers 29 protruding therefrom to engage the inner wall of the bone 9 to exert pressure and generate micro-movement, thus serving as a catalyst to promote the generation of new bone tissue growth into a space 152 contained by the trough portion 21.

Fig. 3A is a longitudinal perspective view of one of the support elements 115 of Fig. 2A. The trough portion 21 may be fitted with an adjustable longitudinal support structure or tension cables 31 made of high-performance materials such as steel, DYNEEMA™, carbon, or aramid fibers such as KEVLAR™, for example. The tension cables 31 may include metal fibers, which serve as x-ray markers for indicating the presence of the implant in an x-ray film. The tension cables 31 are supported by bridge elements 33.

The tension cables 31 may be uncoated or they may be coated or surface-treated with special materials such as hydroxyapatite, such as porous (PHA) and non-porous (NPHA) versions of granular hydroxyapatite, for stimulating bone

calcification; porous bone material; inorganic bovine bone; inorganic zenograft bone mineral; an osteoconductive bone graft substitute (a type of corraline hydroxyapatite), such as that marketed under the name PRO OSTEON™; a bioactive glass implant that bonds to bone and tissue at a fracture site, such as that marketed under the name BIOGLASS™; and COLLAGRAFT™, an FDA-approved osteoconductive and osteoinductive synthetic bone graft substitute that contains a mixture of hydroxyapatite, tri-calcium phosphate, and bovine fibrillar collagen, among other things. The coating may contain bone morphogenic protein and/or prescribed medication for preventing bone diseases.

The tension cables 31 may be wrapped with a randomly woven loose mesh of thin fibers 32, and may also include short whisker reinforcement elements 35 made of the same or similar materials as the tension cables 31. The mesh 32 and the whisker reinforcement elements 35 may be coated with special materials such as hydroxyapatite, with or without bone morphogenic protein and/or prescribed medication for preventing bone diseases, and the whisker reinforcement elements 35 may be included as part of the mesh 32. Preferably, the mesh 32 and the bridge elements 33 are formed of a resorbable material that is absorbed by the patient's body so that they practically disappear within a prescribed period of time.

The presence of such materials as hydroxyapatite, with or without bone morphogenic protein, on the trough portion 21, the mesh 32, and/or the tension cables 31 promotes new bone tissue generation, and the new bone tissue may be specially designed to have a predetermined shape defined by the shape of the trough portion 21, which serves as a mold for the new bone tissue generation. Over time (about one year in some cases), a composite bone is produced with a cross section having a larger moment of inertia than the original moment of inertia of the bone 9, and the composite bone is formed as a substantially continuous longitudinal web 2 that interfaces with the trough portion 21, with or without the high-performance tension cables 31 being embedded therein. The tension cables 31 may be fully or partially embedded within the new bone tissue, and the tension cables may be bonded to the bone 9 by the new bone tissue and/or by an adhesive substance.

Therefore, the implant 10 not only effectively helps to heal a broken bone, it also substantially increases the strength of the healed bone by effectively reforming the bone with a new cross section having a larger moment of inertia (I) than that of the original bone's internal structure, and by incorporating reinforcements, such as the tension cables 31, which may or may not be used to provide adjustable tension control, formed of a material with a

Young's modulus (E) greater than that of natural bone. The overall product of ExI of the composite bone is thus much higher than that of the original or natural bone. Therefore, the danger that the same bone will break again is reduced. The newly-induced bone tissue growth may also incorporate and have embedded therein the whisker reinforcement elements 35, which act to further strengthen the newly-generated bone material.

According to another embodiment of the present invention, bone-growth inducing materials and/or prescribed medications for preventing bone diseases may be included as a coating on the implant 10 or administered by various means as crystals, resorbable capsules, liquids, or powders into open regions or voids in the implant 10.

According to an embodiment of the present invention, whisker reinforcement elements, similar to those of reference numeral 35, made of metal or fibers of carbon, KEVLAR™, or DYNEEMA™, for example, are added to bone cement for improving the strength of a cement layer formed of the whisker-reinforced cement to reduce the occurrence of cracking in brittle types of cement and to improve stability in flexible types of cement. The reinforced bone cement may be used in attaching various bone implants to bone, and may also be used to connect bone segments together.

Fig. 3B shows an embodiment of the present

invention for a stand-alone external bone brace 200, which operates as a bone-structure enhancement device that may also be used to facilitate the generation of composite bone. The bone brace 200 comprises a trough portion 36 formed as a corrugated portion of a thin bone brace 200 integrally attached to a sleeve-flange element 37. Alternatively, the bone brace 200, may be comprised of a trough portion 36 formed as a molded recess (not shown) of a thick bone brace 200. The bone brace 200 may be secured by cement, glue, staples 39, screws, or other means onto the outside of a fractured bone 1, around either the entire circumference of the bone 1 or a part of it, to locally reinforce the bone 1 at specific regions such as at the fractured region 40 to repair the fractured region 40. Optionally, the sleeve-flange element 37 with the attached trough portion 36 may be secured to a region to change the bone curvature of that region.

The trough portion 36 is, in many respects, similar to the trough portion 21 of Fig. 3A, and may be fitted with tension cables 31 such as those described above. The tension cables 31 may or may not be adjustable.

In some cases, preferably in cases where the sleeve-flange element 37 encircles the bone 1, a woven reinforcement bandage (not shown) formed of high-performance materials (such as those described above) may be placed

between the surface of bone 1 and the sleeve-flange element 37. The reinforcement bandage has incorporated therein growth-inducing biological materials to promote bone tissue growth through and around the weave of the bandage, thus promoting the growth of a new bone layer to which the reinforcement bandage is bonded. The woven reinforcement bandage may be constructed as an integral layer of the sleeve-flange element 37 such that some of the fibers of the woven bandage are laminated and bonded into a skin layer of the sleeve-flange element 37.

According to an embodiment of the present invention, the woven reinforcement bandage is fully embedded within the newly generated bone layer. That is, when new bone regeneration occurs, the sleeve-flange element 37 becomes embedded or "cast" into the new bone material and becomes a single structural element with the new bone material.

Fig. 4A is a cross-sectional view of the bone implant 10 showing the core 12 (see Figs. 1A and 3A). The core 12 has a stiffness governed by, among other things, its overall geometry and materials properties. The core 12, the bridge elements 33, and the generally-taut tension cables 31 combine to form a "sailboat's spar" configuration, which is very light and has a much higher combined stiffness than that of the core 12 alone. The bridge elements 33 serve as

"spar spreaders" and may be constructed as a portion of the support element or as a portion of the core 12. Optionally, the composite core configuration may be employed without the spar configuration, and the spar configuration may be employed at only a portion of the implant 10.

The core 12 may be formed of any material, and may have various constructions, such as a solid unit, a hollow unit, an assembly of individual rods, a plurality of rods formed into a truss structure, a mesh of circumferential fibers or wires wound to have a substantial area of open voids, or helical (coiled) springs.

The tension cables 31 may be anchored at any location of the implant 10, such as at anchoring points 81, 82, or other alternative locations, and the tension in the tension cables 31 may be controlled and adjusted during the course of the implantation operation at any time during and after insertion of the implant. Therefore, the tension in the tension cables 31 may be adjusted after the implant is inserted into and positioned within the bone canal 4, and may even be further adjusted at future times after the implantation operation.

The tension cables 31 are adjusted using a tensioning device 34, which may include a multi-pin ratchet means or other means that enable the tensioning device 34 to change or adjust the tension in the tension cables 31 and

also to cut extraneous lengths of the tension cables 31 after tensioning thereof. The tension cables 31 may be adjusted to provide stiffness to at least a portion of the implant 10, and they may also be used to produce a curved profile in at least a portion of the implant 10 so that the curved portion has a substantially identical profile as that of the bone canal 4, even while outside of the bone canal 4. The above-described tension system is an "even tension" type of tension system.

According to an embodiment of the present invention, the tensioning device 34 may be used to produce a controlled and uneven tension in the tension cables 31 to simulate a bending moment in the bone. Implants 10 having tension cables 31 with an uneven or non-uniform tension thereof may be used as a loaded element that continuously acts on the bone to change its curvature over time. Therefore, such tension cables 31 may be used to correct undesired curvature in bones, and the correction process may include periodic adjustments of the tension in the tension cables 31 to progressively correct the undesired bone curvature.

As an alternative, whisker reinforcement elements 35 may be included in some trough portions 21 of the implant 10 and not in others to produce controlled stress regimes which may be used to exert controlled levels of stress to

selected areas of the bone 9 to thereby achieve bone curvature correction. The presence of whisker reinforcement elements 35 in newly generated bone tissue changes the characteristics of the bone as compared with natural bone tissue without the presence of the whisker reinforcement elements 35.

According to another embodiment of the present invention, the implant 10 may be constructed to include tension cables 31 but not include trough portions 21 by using various "spreaders means" such as the support elements 15, shown in Fig. 1C, at least for the purpose of controlling stiffness and curvature, or as a longitudinal cable 60 integrally woven into a sleeve element 62, as shown in Fig. 5.

Fig. 4B shows an embodiment of the core 12 formed of a composite material and constructed to have one or more tapered ends 48. Positioned between a pair of knuckles 51 is a middle section 50 having either a constant or varying cross-sectional diameter. The composite material may include a number of different fiber types, orientations, and diameters to optimize the desired stiffness for different portions of the core 12. The middle section 50 is designed to be the stiffest part of the core 12 so that it may provide stability to bone regions that most require stiffness, such as near an articulating joint portions or at

a fractured bone region, while the tapered ends 48 are sufficiently flexible to enable easy insertion of the implant 10 into the bone's three-dimensionally curved canal and, at the same time, provide good anchoring to the bone. The tapered ends 48 become stiffer after insertion into the bone through a tensioning action of the tensioning cables 31, as described above.

According to a preferred embodiment, the core 12 is formed of at least two types of materials each having a different Young's modulus, and the at least two types of materials are arranged to provide a varying Young's modulus along a longitudinal axis of the core 12.

Fig. 4C is a longitudinal cross-sectional view showing a tension cable 31 anchored to a trough portion 21. The trough portion 21 may have a natural slightly curved profile such that the tension cable 31 is supported on only a part of end bridge elements 33. When fitted into the slots 25 in the molded interface portion 13 (shown in Fig. 2B), the trough portion 21 straightens and is kept straight by the raised or serrated walls 26 that produce a secure fit, as described above with respect to Figs. 2A and 2B, or by holding means which may be of a ring type (not shown) that prevents the trough portion 21 from reverting to its original curved shape. This creates a pre-designed tension in the tension cable 31, and the tension is similar to that

in strings on a musical instrument or stays on a sailboat spar fitted with spreaders. This insertion tension may be the final tension of the assembled implant or, alternatively, the insertion tension may be an auxiliary tension, with a higher final tension exerted by the action of the tensioning device 34. Adjustments to the tension in one or more tension cables 31 may be made during the course of the implantation operation or after insertion of the implant, such that final tension adjustments are made only after the device has been inserted into and positioned within the bone canal 4, as mentioned above.

The implant 10 and the treated bone 9 may thus form two structure types: one in which the implant 10 is transformed into the bone 9, and one in which the implant 10 is superimposed with the bone 9.

According to the first structure type, an assembly of three components —a composite core 12, bridge elements 33, and tension cables 31— is transformed into a structure that comprises natural bone, bone tissue generated as bone webs 2, and tension cables 31. These components become incorporated in a composite bone structure when new bone web tissue is generated that fills the trough portion 21 and embeds the tension cables 31 within the newly generated bone web tissue, thereby reinforcing the web tissue. Other portions of the implant 10, excluding the tension cables 31

may be removed from the patient.

According to the second structure type, an assembly of the three components —a composite core 12; bridge elements 33; and tension cables 31— is superimposed with a structure that comprises natural bone, bone tissue generated as bone webs 2, and tension cables 31. These components become incorporated in a composite bone structure when new bone web tissue is generated that fills the trough portion 21 and embeds the tension cables 31 within the newly generated bone web tissue, thereby reinforcing the web tissue.

Fig. 5 is a perspective view showing a longitudinal cable 60 and support element 15 according to another embodiment of the present invention. The longitudinal cable 60 may be part of a woven sleeve element 62 made of high-performance fibers of DYNEEMA™, carbon, or KEVLAR™, for example. Groups of fibers are woven into various layers and have various orientations such as diagonal, longitudinal, and circumferential, for example, and may also have open areas 44 in the weave. The sleeve element 62 may be attached to the support element 15 or to the trough portion 21 by various click-on means (not shown), by using one or more bridge elements 33, or by using one or more channeled grooves 20A (see Fig. 1C).

The sleeve fibers may contain special materials

such as hydroxyapatite, with or without bone morphogenic protein. Additionally or alternatively, the sleeve element 62 may include regions containing a loose mesh 32 of thin fibers made of the same or similar materials as the sleeve element 62, and may also contain special materials such as hydroxyapatite, with or without bone morphogenic protein, or a prescribed medication, such as that for fighting bone or bone marrow diseases. Optionally, the sleeve element 62 may be wrapped with the loose mesh 32.

The implant 10 is inserted into the sleeve element 62 and the sleeved implant is then inserted into the bone canal 4, with the sleeved implant snugly contacting the bone 9 at a plurality of generally continuous locations. Optionally, a lining 63 may be interposed between the implant 10 and the sleeve element 62, and may be constructed to flexibly assist in pressing the sleeve element 62 against the bone canal 4 to promote a substantially continuous contact between the implant 10 and the bone canal 4. At the contact regions, the presence of growth-inducing biological materials helps to promote bone tissue growth through and around the weave, thus creating a new bone layer to which the sleeve element 62 becomes bonded. In one embodiment, the sleeve element 62 becomes fully embedded within the new bone layer, thus creating the composite bone described above. The openings 44 are designed to encourage spearheads

of bone growth to penetrate the weave quickly, and then gradually spread laterally until a generally uniform layer of new bone tissue is generated. The mesh 32, the whisker reinforcement elements 35, and/or the tension cable 60 act to promote bone tissue generation to conform to a predetermined desired shape defined by the trough portion 21, which also serves as a form or mold for embedding the tension cable 60 in the newly generated bone tissue.

Thus, bone growth into the trough portion 21 and/or the sleeve element 62 may occur in a number of ways:

(a) by natural bone regeneration with time;

(b) by application of pressure using various implant portions;

(c) by micro-movement and/or vibration of portions of the implant relative to the bone canal;

(d) by micro-movement and/or vibration of fixed or resorbable whisker reinforcement elements relative to bone canal; and

(e) by administering various bone-growth promoting materials.

The composite bone and the structurally improved implants of the present invention may be employed in cases where no bone fracture is present but where bone reinforcement is necessary and desired. The implant 10 may be used as a "non-structural device" made of a relatively

thin skin of a material such as polyethylene, for example, which is easily inserted into the sleeve element 62 and which may include the tension cables 31, the mesh 32, and/or the whisker reinforcement elements 35. Such a device is inflated by fluid pressure to press against the wall of the bone canal 4.

According to yet another embodiment of the present invention, at least one region of the interface portion 13 may be inflatable and filled with fluid to create pressure regions which, in turn, exert forces on the support members 15 and the wall of the bone canal 4 to effect anchoring of the implant 10 and/or to produce a snug fit of the implant 10 within the bone canal 4 to thereby enhance the micro-movement of the implant 10 relative to the bone canal 4.

According to still another embodiment of the present invention, and with reference to Fig. 1A, a flexible implant is constructed without a core element 12, thus making the implant extremely flexible and easy to insert into the bone canal 4. The interface portion 13 of the flexible implant may be reinforced by high-pressure tubing made of fibers of materials such as steel, nylon, polyester, KEVLAR™, and DYNEEMA™, for example. By filling the area surrounded by the interface portion 13 with fluid, which exerts pressure on the interface portion, the flexible implant is transformed from an extremely flexible state to a

substantially rigid state. The pressure exerted by the fluid on the interface portion 13 also acts to press the support elements 15 against the wall of the bone canal 4, thereby producing an optimal fit and good anchoring of the flexible implant in the bone canal 4.

For an implant such as that shown in Fig. 5, the pressure exerted by the fluid on the interface portion 13 presses the sleeve element 62 against the wall of the bone canal 4 to produce a nearly continuous contact between the sleeve element 62 and the wall of the bone canal 4 over a substantial portion of the sleeve element 62. Optionally, if a lining 63 is used in the flexible implant, the interface portion 13 presses the lining 62 which, in turn, presses the sleeve element 62 against the wall of the bone canal 4.

Once the interface portion 13 is pressurized with fluid, the tension cables 31 may be adjusted to produce desired tension levels in various parts of the flexible implant.

The flexible implant described above may be provided with short sections of a core element 12 at specific portions of the flexible implant to provide support to those portions.

Optionally, the flexible implant may contain time-release capsules (not shown) that emit controlled amounts of

medication into the bone canal 4 over an extended period of time. The time-release capsules may be positioned wherever there is sufficient space available in the flexible implant.

Figs. 6A and 6B are cut-away views showing an embodiment of the present invention as applied to a stem implant such as a hip replacement stem implant. The hip replacement stem implant produces a continuous longitudinal webs 2 reinforced with tension cables 31 embedded therein, and these webs 2 extend beyond the end point 80 of a conventional stem implant. Therefore, overall bone strength is reinforced along the entire femur 85, and the stem implant forms a gradual transition from implant to composite bone to bone.

According to yet another embodiment of the present invention, improvements are made to conventional interlocking nail systems.

In a conventional interlocking nail system a metal nail is used, and the nail has through-holes pre-drilled therein. During the implantation operation the surgeon drills through the bone and must take care to align the bone holes with the pre-drilled holes in the nail. The pre-drilled metal nails are usually coated with a bio-compatible material and, therefore, it is desirable to preserve the integrity of that coating. Screws are then inserted through the holes in the metal nail and are self-tapping with the

holes in the bone. This interlocking process prevents axial movement of the bone relative to the nail and ensures that two fractured bone portions are joined and prevented from separating and forming an undesirable space therebetween.

The present invention improves on the conventional interlocking nail system by not requiring the surgeon to align the holes drilled in the bone with the pre-drilled holes in the metal nail, which is a very difficult task to perform during the surgical operation and often results in poorly fitted implants. Instead, according to an embodiment of the present invention, the nail is made of a drillable material so that the surgeon can drill directly through the bone and the nail without having to worry about whether the bone holes align with the nail holes. In addition, the drilling can be accomplished at any desired angle and orientation and is not limited by the presence of pre-drilled holes in the nail.

According to another embodiment of the present invention, shown in Fig. 7, a plastic sleeve 75 is inserted into a pre-drilled hole in a metal nail 74. During the implantation operation, the surgeon drills through the bone 70 and then through the plastic sleeve 75. The plastic sleeve 75 may initially contain a small hole or an elongated slot (not shown) or no hole at all. The plastic sleeve 75 acts to grip the screw 76 to prevent it from sliding in the

direction a-a inside the pre-drilled hole in the metal nail 74. The diameter of the pre-drilled holes in the metal nail 74 is necessarily larger than the outer diameter of the threads 77 of the screw 76 because otherwise the screw 76 cannot be inserted therein. The drilled hole in the plastic sleeve 75, however, may be smaller than the outer diameter of the threads 77 of the screw 76 so that the threads 77 of the screw 76 cut into the plastic material of the sleeve 75. According to a preferred embodiment, the sleeve 75 is made of an FDA-approved polyethylene.

The embodiments described above are illustrative examples of the present invention and it should not be construed that the present invention is limited to these particular embodiments. Various changes and modifications may be effected by one skilled in the art without departing from the spirit or scope of the invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A deformable bone implant, comprising:

a interface portion for interfacing with a bone; and

a support structure for supporting the interface portion.

2. A deformable bone implant according to claim 1, wherein the support structure is comprised of a central core.

3. A deformable bone implant according to claim 1, wherein the support structure is comprised of a truss-like structure of rods.

4. A deformable bone implant according to claim 1, wherein the support structure is comprised of a mesh of fibers or wires arranged to have opens areas within the mesh.

5. A deformable bone implant according to claim 1, wherein the support structure is comprised of at least one helical spring element.

6. A deformable bone implant according to claim 1, wherein the support structure is formed of at least two types of materials each having a different Young's modulus, and the at least two types of materials are arranged to provide a varying Young's modulus along a longitudinal axis of the support structure.

7. A deformable bone implant according to claim 1, wherein the support structure comprises an inflatable portion.

8. A deformable bone implant according to claim 1, wherein the interface portion comprises a plurality of support elements protruding therefrom.

9. A deformable bone implant according to claim 8, wherein at least a portion of each of the plurality of support elements is resiliently deformable.

10. A deformable bone implant according to claim 8, wherein at least one of the plurality of support elements is adapted to fit snugly within a bone canal.

11. A deformable bone implant according to claim 8, wherein the plurality of support elements comprises

protrusions that resiliently deform and deflect during insertion of the bone implant into a bone canal such that the plurality of support elements exerts a force against a wall of the bone canal and the implant fits snugly within the bone canal.

12. A deformable bone implant according to claim 1, further comprising an adjustable cable for adjusting a tension in the support structure to thereby adjust stiffness and/or curvature of the implant.

13. A deformable bone implant according to claim 12, wherein the adjustable cable is supported by at least one bridge element.

14. A deformable bone implant according to claim 1, further comprising a plurality of adjustable cables for adjusting a tension in the support structure to thereby adjust stiffness and/or curvature of the implant.

15. A deformable bone implant according to claim 14, wherein the adjustable cables are adjusted to provide an asymmetric or non-uniform level of tension to the plurality of adjustable cables.

16. A deformable bone implant according to claim 14, wherein the adjustable cables are adjusted before, during, and/or after implantation of the bone implant.

17. A deformable bone implant according to claim 14, wherein the adjustable cables are adjusted to provide a variable rigidity to the bone implant.

18. A deformable bone implant according to claim 1, wherein the interface portion contains at least one type of prescribed medication that is administered into a bone canal of the bone.

19. A deformable bone implant according to claim 18, wherein the interface portion is coated with a material selected from the group consisting essentially of a hydroxyapatite-based substance, a porous bone substance, an inorganic bovine bone substance, an osteoconductive bone graft substitute, and a synthetic bone graft substitute.

20. A deformable bone implant according to claim 19, wherein the material contains a bone morphogenic protein and/or medication for preventing bone diseases.

21. A bone brace, comprising:

a longitudinal sleeve element for encircling at least a portion of an outer circumference of a bone; and

a trough portion attached to the longitudinal sleeve element and facing the bone.

22. A bone brace according to claim 21, wherein the trough portion is comprised of a corrugated portion.

23. A bone brace according to claim 21, further comprising an adjustable cable for adjusting a tension in the longitudinal sleeve element to thereby adjust stiffness and/or curvature of the bone brace.

24. A bone brace according to claim 23, wherein the cable is supported by at least one bridge element.

25. A bone brace according to claim 21, further comprising a plurality of adjustable cables for adjusting a tension in the longitudinal sleeve element to thereby adjust stiffness and/or curvature of the bone brace.

26. A bone brace according to claim 25, wherein the adjustable cables are adjusted to provide an asymmetric or non-uniform level of tension to the plurality of adjustable cables.

27. A bone brace according to claim 25, wherein the adjustable cables are adjusted before, during, and/or after installation of the bone brace.

28. A bone brace according to claim 25, wherein the adjustable cables are adjusted to provide a variable rigidity to the bone brace.

29. A bone brace according to claim 21, wherein the trough portion is coated with a material selected from the group consisting essentially of a hydroxyapatite-based substance, a porous bone substance, an inorganic bovine bone substance, an osteoconductive bone graft substitute, and a synthetic bone graft substitute.

30. A bone brace according to claim 29, wherein the material contains a bone morphogenic protein and/or medication for preventing bone diseases.

31. A bone brace according to claim 21, further comprising a woven reinforcement bandage positioned between the brace and the bone, wherein at least a portion of the bandage is molded with the longitudinal sleeve element and/or the trough portion.

32. A bone brace according to claim 21, further comprising a liner positioned between the trough portion and the bone.

33. A bone brace according to claim 32, wherein the liner is molded with the longitudinal sleeve element and/or the trough element.

34. A bone implant, comprising:

a longitudinal sleeve element for at least partially encircling an outer circumference of a bone; and

a plurality of support elements attached to the sleeve element and contacting the bone, wherein

the sleeve element including the plurality of support elements becomes embedded in newly-generated bone tissue to form a composite bone structure.

35. A bone implant, comprising:

an interface portion supported by a support structure; and

a plurality of resiliently deformable support elements protruding from the interface portion, wherein

the plurality of support elements contact a wall of a bone canal such that the implant conforms to and fits snugly within the bone canal, and

the plurality of support elements comprising protrusions that resiliently deform and deflect during insertion of the implant into the bone canal such that the plurality of support elements exert a force against the wall of the bone canal.

36. A bone implant according to claim 35, wherein the plurality of support elements comprises longitudinal support members contacting the wall of the bone canal over substantially continuous portions of the support members.

37. A bone implant according to claim 35, wherein the plurality of support elements comprises a group of adjacent elements positioned in a substantially longitudinal manner with respect to the bone canal, the group of adjacent elements contacting the wall of the bone canal over a substantially continuous portion thereof.

38. A bone implant according to claim 35, further comprising at least one elongated tension member attached to the interface portion, wherein the at least one tension member becomes embedded in newly generated bone tissue and/or bonded to the wall of the bone canal to form a composite bone structure.

39. A bone implant according to claim 35, wherein each support element comprises a trough-like element which contacts the wall of the bone canal to serve as a catalyst for bone tissue growth.

40. A bone implant according to claim 39, wherein the trough-like element comprises a plurality of fingers for engaging the wall of the bone canal.

41. A bone implant according to claim 38, wherein at least a portion of the elongated tension member is surrounded with a loosely woven mesh of fibers and/or whisker reinforcement elements.

42. A bone implant according to claim 41, wherein the elongated tension member, the woven mesh, and/or the whisker reinforcement elements are coated with at least one material selected from the group consisting essentially of a hydroxyapatite-based substance, a porous bone substance, an inorganic bovine bone substance, an osteoconductive bone graft substitute, a synthetic bone graft substitute, bone morphogenic protein, and medication for preventing bone diseases.

43. A bone implant according to claim 38, wherein

the elongated tension member is supported by at least one bridge element attached to the interface portion.

44. A bone implant according to claim 38, wherein the elongated tension member is attached to the interface portion with an adhesive.

45. A bone implant according to claim 35, further comprising a woven sleeve element surrounding the plurality of support elements.

46. A bone implant according to claim 45, wherein the woven sleeve element comprises an elongated tension member.

47. A bone implant according to claim 45, further comprising a lining interposed between the woven sleeve element and the support elements for flexibly pressing the woven sleeve element against the wall of the bone canal.

48. A bone implant according to claim 47, wherein the woven sleeve element and/or the lining extends beyond an end of the support structure to interface the wall of the bone canal.

49. A bone implant according to claim 35, wherein the support structure is comprised of a truss-like structure of rods.

50. A bone implant according to claim 35, wherein the support structure is comprised of a mesh of fibers or wires arranged to have open areas within the mesh.

51. A bone implant according to claim 35, wherein the support structure is comprised of at least one helical spring element.

52. A bone implant according to claim 35, wherein the support structure is formed of at least two types of materials each having a different Young's modulus, and the at least two types of materials are arranged to provide a varying Young's modulus along a longitudinal axis of the support structure.

53. A bone cement for a bone implant, the bone cement comprising:

a cement material; and

whisker reinforcement elements mixed with the cement material, wherein

the whisker reinforcement elements are comprised

of metal or non-metal fibers.

54. An intramedullary implant, comprising a nail formed of a drillable material.

55. An intramedullary implant according to claim 54, wherein the nail has pre-drilled holes and further comprising plastic portions within the pre-drilled holes.

56. An intramedullary implant according to claim 55, wherein the plastic portions have openings therein.

ABSTRACT OF THE DISCLOSURE

A stem-like bone implant includes longitudinal structural members and tension cables that provide curvature control and support, and rigidity against bending and buckling. The longitudinal structural members and tension cables may become an integral part of a composite regenerated bone having a substantially increased strength over natural bone. The flexibility of the implant is controlled by specifically varying the structural geometry of certain portions of the implant, and by adjusting the tension in the tension cables before, during and after the implantation operation to thereby adjust the stiffness of the implant. The tension cables may be adjusted to produce asymmetric or non-uniform levels of tension in the longitudinal structural members.

FIG. 1A

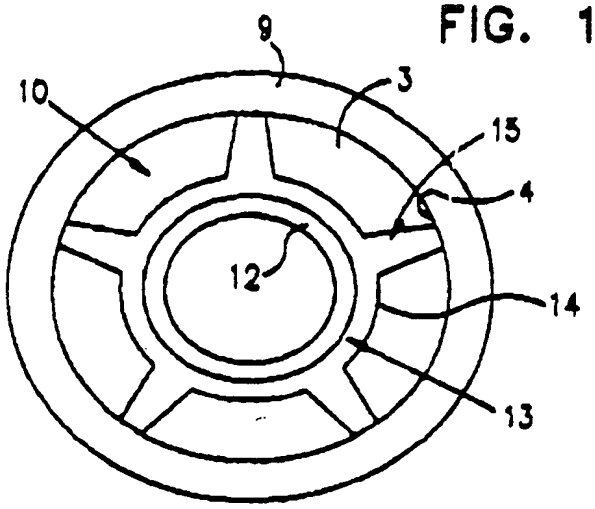
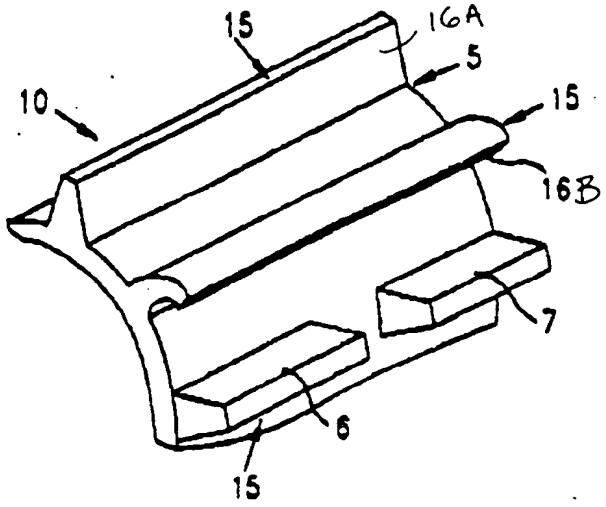


FIG. 1B



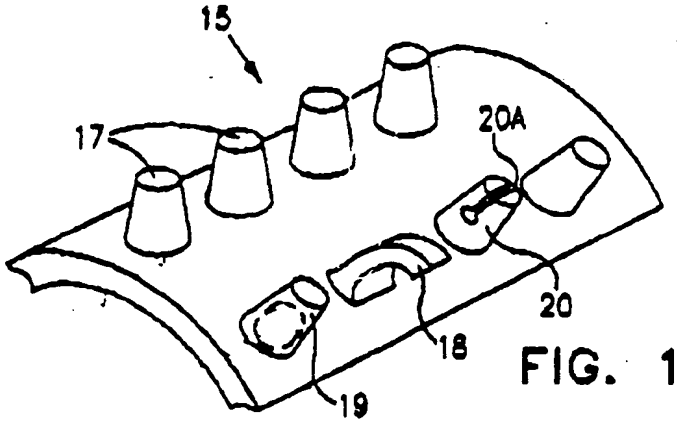
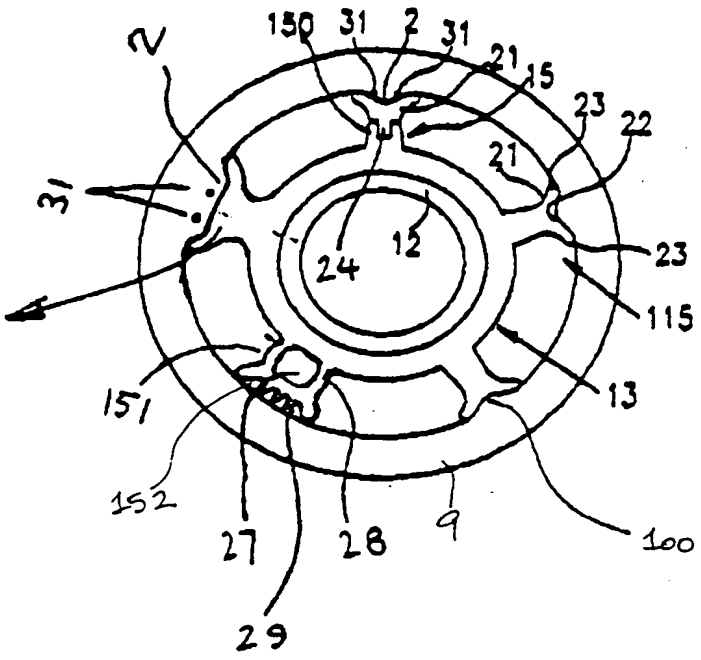


FIG. 1C

FIG. 2A


150
31
2
31
21
15
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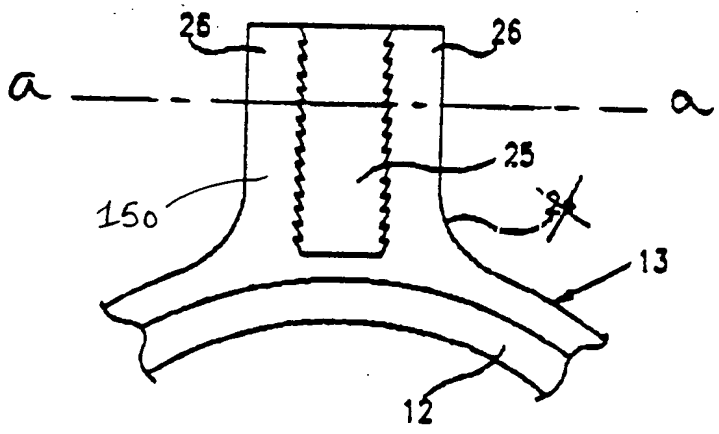
22
21
31
24
12
23
115
13
151
152
27
28
9
100
29

FIG. 2B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a
a
25
150
13
12

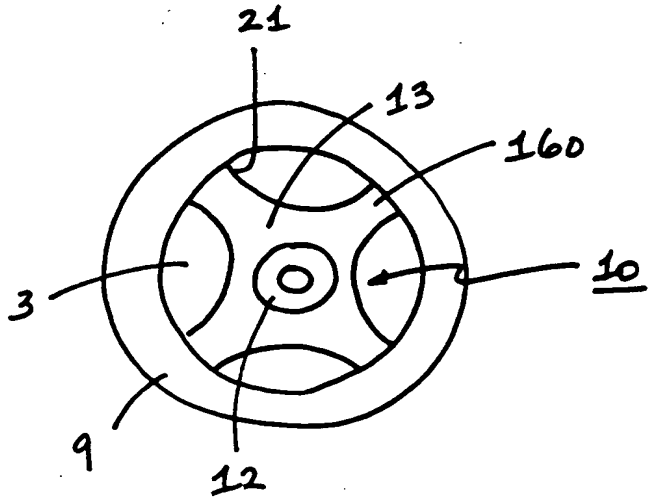
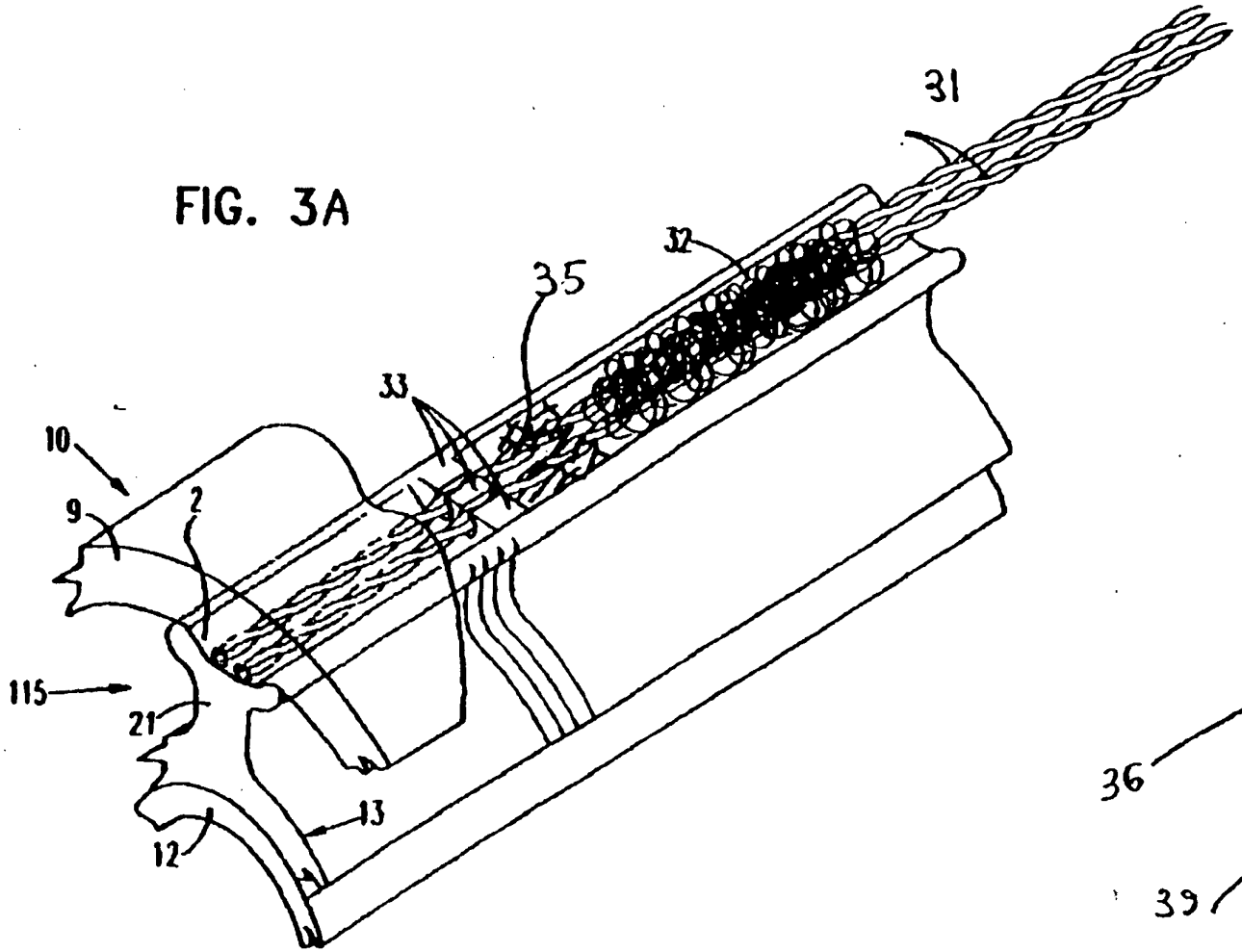


FIG. 2C

FIG. 3A



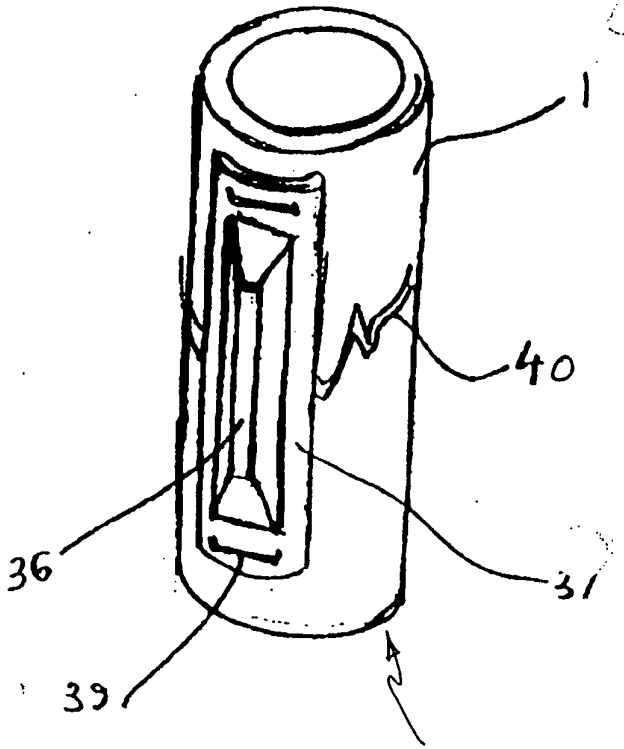


FIG 3B

FIG. 4A

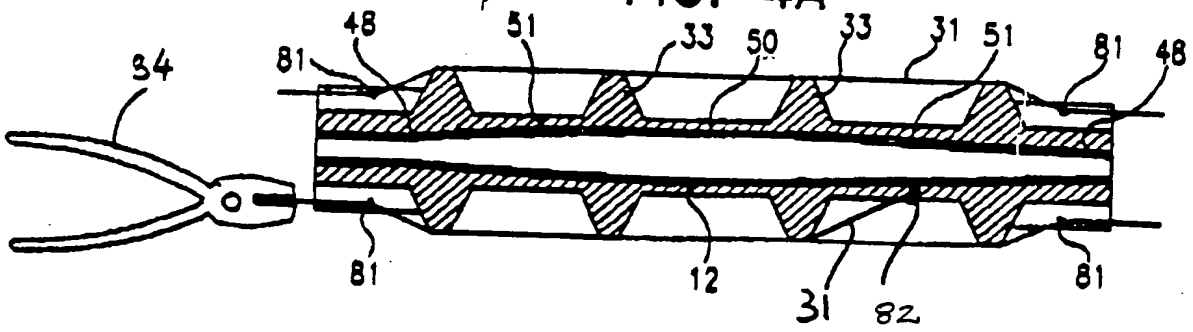


FIG. 4B

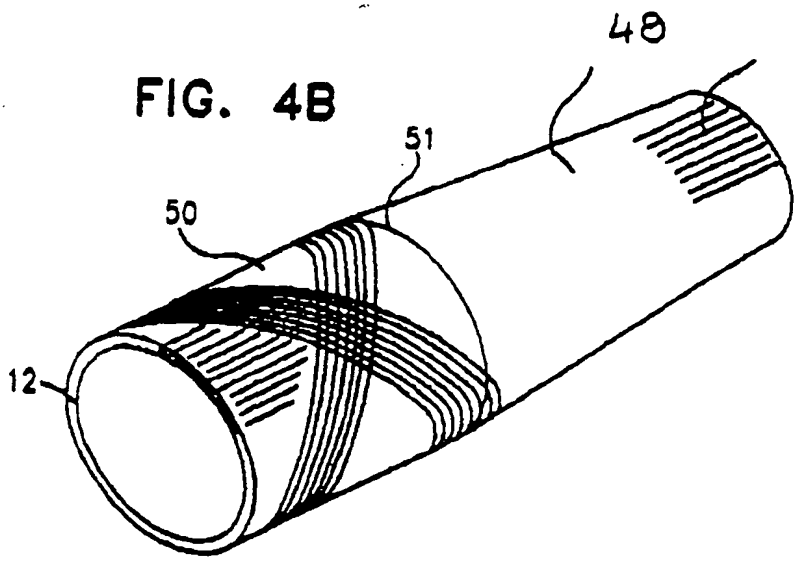
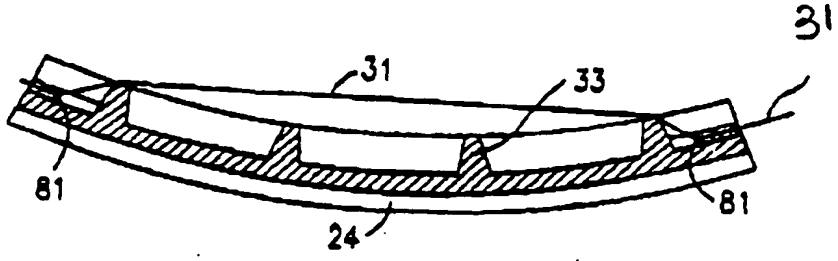


FIG. 4C



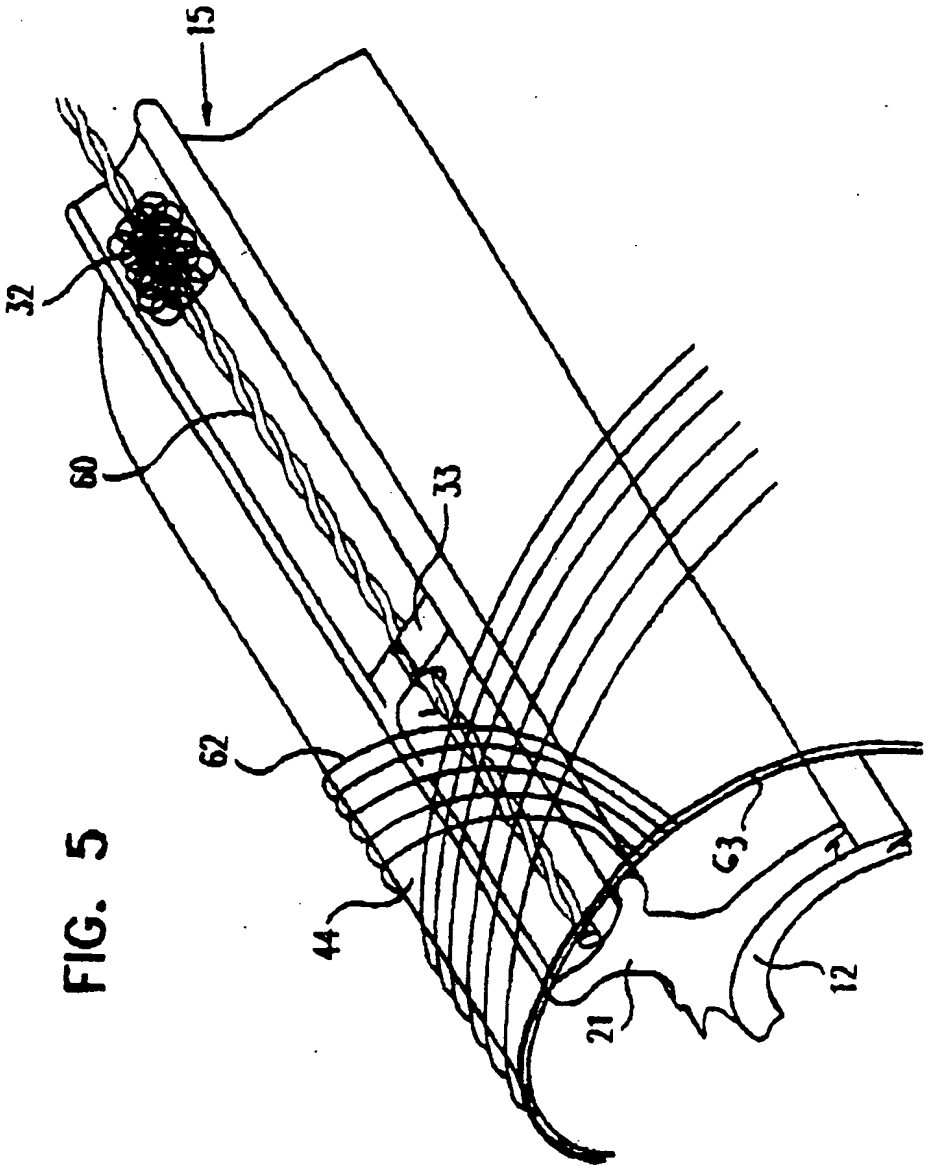


FIG. 5

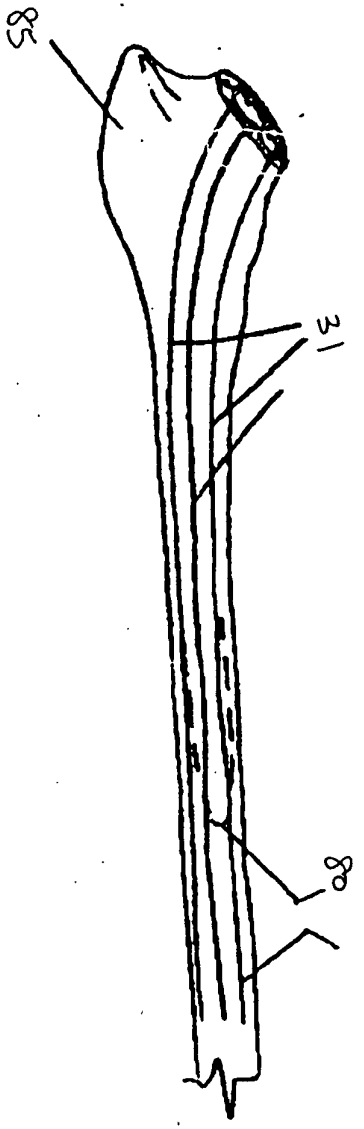


FIG. 6B

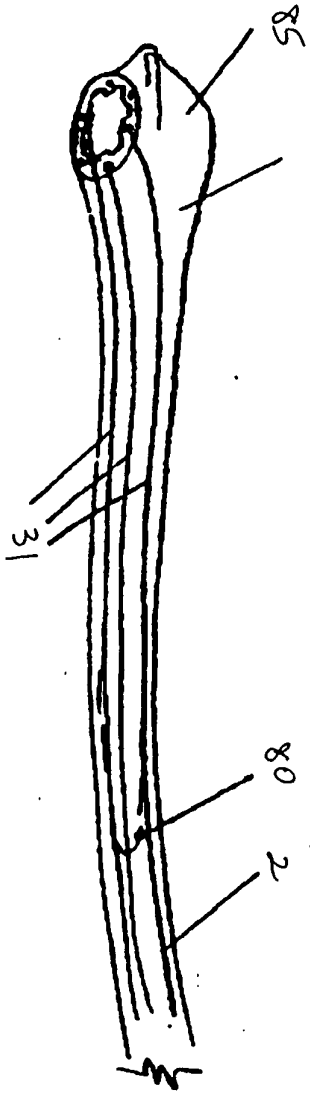


FIG. 6A

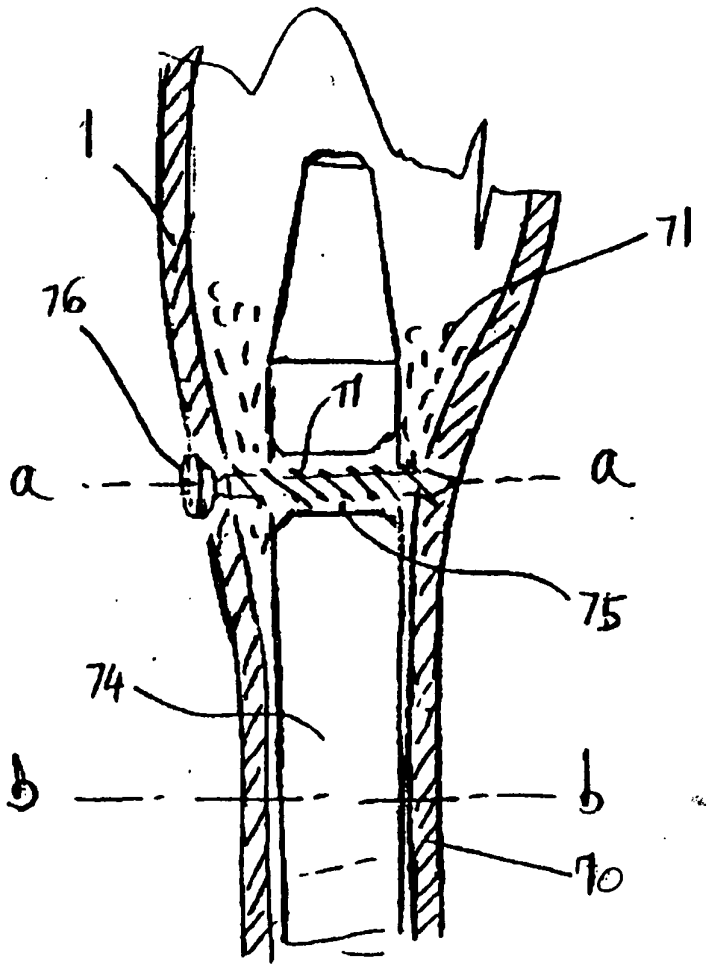


FIG. 7